*Standards Alliance: Phase 2*

# Quarterly Report

*Q1 January 1st- March 31st 2023*

**Submission Date: May 31, 2023**
**Version 2**

Agreement Number: 7200AA19CA00012
Activity Start Date and End Date: July 12, 2019 to July 11, 2026
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This document was produced for review by the United States Agency for International Development (USAID).

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# 1. PROGRAM OVERVIEW/SUMMARY

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| **Program Name:** | Standards Alliance: Phase 2 |
| **Activity Start Date And End Date:** | July 12, 2019 – July 11, 2026 |
| **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 January 1st- March 31st 2023 |

## 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 2023 continued with the implementation of all activities under the approved subawards. The ASTM subaward held an in-person workshop in Dakar, Senegal to promote and solidify the work the project has done around petroleum standards harmonization in West Africa, facilitating cross border trade with the partner countries. Additionally, ICONTEC is working with INVIMA to provide more in-depth information to the PPE guide in Colombia on COVID-19-related PPE, as masks, gowns, and gels are considered "medical equipment" and therefore not covered by ICONTEC. A final, translated draft is expected by the middle of Q3, with promotion of the guide to follow.

## 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

The last event for this activity was the virtual 2-day bioethanol standardization workshop which was held in Mali on September 13-14, 2022. As stated in past reports, the event was open to local stakeholders including government ministries, clean cooking associations, standards organizations, development organizations, local businesses, and served as an introduction to bioethanol and the importance of smart policy and standards.

Building on the efforts undertaken during the last quarter, during Q1 2023 AMANORM (the Mali national standards body) and ASTM signed a Memorandum of Understanding (MoU) to work together on renewable fuels.

Additionally, in partnership with ARSO, a Standards and Quality Control (QC) webinar was organized in February of 2023. The training focused on bioethanol as an alternative to toxic fuels like wood and charcoal that are commonly used for cooking on the African continent. This event concluded a five part webinar series on this topic and Pivot is now coordinating with ARSO to implement in the long term the lessons learned during the training. Pivot will include outcomes and lessons learned for the activity in the upcoming annual report. Additionally, Pivot is also developing a concept note for future SA2 engagement, incorporating feedback provided by ANSI and USAID in March 2023.

Working with ARSO continues to expedite benefits of transitioning to clean fuels by providing a platform to discuss problems related to solid fuels, solutions presented by bioethanol, and engaging local stakeholders to inform on target geographies. This collaboration ensures countries are informed, prepared, and supportive of bioethanol while creating an enabling environment for an emerging commodity. As demonstrated in other markets, harmonized regional standards improve market predictability and transparency, which will support U.S. – Africa bilateral cooperation and trade.

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

Partner countries: Continent Wide

During this quarter Personal Care Product Council (PCPC) and ANSI worked on the final webinar on Good Manufacturing Practices for Cosmetics; which follows the last webinar in May 2022. For the final webinar, which took place on February 28, 2023, experts from PCPC continued to underline the importance and role of consumer protection in assuring compliance with labeling requirements set by cosmetics industries. Speakers expanded upon labeling practices for cosmetics in the U.S., EU, and Africa and provided top-level insight into aspects of labeling harmonization, eliminating barriers to trade in cosmetics and enabling the African Continent Free Trade Area (AfcFTA). Although this was PCPC's final

activity under the Standards Alliance, PCPC reaffirmed its intent to provide more capacity building to support African industries as they continue to take up regulatory frameworks that are based on international best practices for labeling. The objective of the overall series has been to ensure a higher level of safety and quality of products so that the African continent may gain more competitiveness in this sector and thus be able to more fully participate in the global value chain for cosmetic products. PCPC will include outcomes and lessons learned in the upcoming annual report.

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

Partner countries: Ghana, Uganda, and Zambia

Activity #3.2 – Conduct in-person or virtual interviews with Ministries, regulators, National Standards Bodies, utilities, private sector partners and civil society organizations

The CWSC continues to review the results of interviews with stakeholders that began in Q4 2022. It completed eight (8) interviews in Q4, but has several additional stakeholders it anticipates reaching out to in Q2 2023, following the completion of the country-level draft reports. CWSC also anticipates that IAPMO may have additional suggestions for people with whom we should speak.

Please see the Q4 2022 Report for the list of stakeholders interviewed in Q4 2022. The CWSC did not interview any additional persons in Q1 and focused on completing draft reports in full.

Activity #3.3 – Incorporate findings from deskwork and interviews into comprehensive country-level reports

The CWSC began drafting each country report in Q4 2022. The CWSC completed full drafts of the country-level reports and shared them in late March 2023. CWSC anticipates completing a full draft of the trend report in Q2 2023 now that it has a clear idea as to what exists in each country's laws.

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

Partner countries: Lesotho, Malawi, and Zambia

Activity #8.3 – Conduct training with participants from Zambia, Malawi, and Lesotho water utilities

A second virtual workshop was completed on January 10th and 11th, with monthly follow up calls on February 7 and March 16. The virtual workshop lasted approximately 3-1/2 hours each day and was attended by participants from at least 12 organizations and included 40 individual participants from water and wastewater utilities from Lesotho, Zambia, and Malawi. All attendees were provided with pdf versions of third and fourth ANSI/AWWA Standards to be covered in the workshop series (ANSI/AWWA G520 – Wastewater Collection Systems Operation and Management, and ANSI/AWWA G510 – Wastewater Treatment Plant Operation and Management).

A third and final workshop will take place on April 25th and 26th in Livingstone, Zambia, with a strong

demand from local stakeholder to have an in-person training to facilitate exchange and lessons learned from the event. 44 individuals are expected to attend the in-person workshop.

## 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

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

In order to continue the implementation of the project and seek further harmonization around petroleum standards in the region, the team in this reporting period conducted key meetings with regional and national SDOs to discuss further trainings.

On March 27th ASTM's technical consultant and three of the technical focal points participated virtually in ASTM's Gasoline: Specifications, Testing, and Technology Course. This extensive class provided broad coverage of the specifications, testing, technology, and regulations related to gasoline. The course also covered an introduction to ASTM's D02 Committee. (Subcommittee on Gasoline), as a precursor to the planned June 2023 U.S. Study Tour.

Activity #5.6 – Conduct regular web conferences with working groups.

During Q1, much time was spent planning and executing an in-person Workshop for eight focal points in Dakar, Senegal, from March 20-22. Both public and private stakeholders participated and the training included a visit to the Société Africaine de Raffinage (SAR) refinery and the local SGS laboratory. The March 2023 event in Senegal was the third in a series of in-country workshops, following one in Ghana in March 2022 and one in Nigeria in July 2022. The Workshop was organized in conjunction with the Association Sénégalaise de Normalisation (ASN) who helped to ensure that the attendance of our focal points from the four countries was accompanied by the appropriate stakeholders from Senegal.

During the workshop the Secretary General from the Senegalese Ministry of Petroleum and Energy delivered a welcome speech, as did the Director of the Senegalese Standards Body (ASN) and the Deputy Director from the USAID Office of Economic Growth. The Event also received coverage by local Senegalese Press: https://afrikbreakingnews.com/2023/03/21/normes-petrolieres-en-afrique-de-louest-une-3eme-formation-des-intervenants-a-dakar/. One particular private sector participant from SGS Senegal SA, who provides local testing services, was deeply involved in the discussions and has followed up with his plans to attend the upcoming June meetings at his own cost.

The U.S. Study Tour, which was expected to take place in December 2022, had to be postponed as a result of delays in obtaining the required J-1 Visas necessary for the West African participants. As stated

in the Q4 report the Study Tour is now scheduled to take place at ASTM's next Committee meeting on the petroleum topic from June 25-29, 2023, in Denver, Colorado. In order to maintain the momentum built with the program to-date and to provide learning opportunities for the delegates in this instance, the focal points were required to attend two virtual sessions on December 5-6, 2022 which were able to be arranged on short notice with the cooperation of Committee leaders. Additionally, three of the four focal countries made virtual presentations on the state of the petroleum industry in their individual countries to the ASTM Committee D02.93.02 on Global Updates and International Liaison Reports on December 8, 2022.

## 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.

Implementation of the original work plan has closed at the end of 2022. The activities faced significant challenges last year in Kenya, Uganda, and Tanzania, due to a lack of familiarity with ACI standards.

During the last reporting period, ACI took the following steps to investigate a new strategy to see whether it would be worthwhile to propose a new subaward:

- **Research appropriate organizations (mainly engineering associations) who might be interested in partnering with ACI.** The Federation of African Engineering Organizations (FAEO) was identified as the perfect partner for ACI. The signing of an International Partner Agreement with FAEO was carried out in October 2022. ACI attended the conference as part of their fact-finding research to revise their strategy and to also solidify contacts and plans for an updated proposal. In late Q3/ early Q4 ACI proposed some changes to their upcoming activities and target countries. In response, USAID provided some feedback on the suggested changes which indicated that a more thought-out approach would be necessary to justify extending their project. The trip to Kigali helped confirm their new approach and solidify the necessary relationships.
- **Leverage Nigerian contacts made at the online ACI Seminar in August 2022.** Particularly the Federal University of Technology who introduced ACI to the Council of Registered Builders of Nigeria (CORBON), and after several virtual meetings, both parties agreed to sign an International Partner Agreement (IPA) in November 2022. Since CORBON is empowered to regulate the practice of building construction, maintenance, and management in Nigeria and also to regulate and control the practice of the building profession in all its aspects and ramifications, it became clear that establishing a relationship is in the best interests of both parties. CORBON has communicated to ACI that they are interested in the ACI Certification Program and ACI University to increase concrete knowledge throughout Nigeria.

- **Participation in the December 2022 Big 5 – Dubai Exhibition.** On the opening day of the event, ACI President and the team participated in the Big 5 Global Construction Leaders' Summit where the CEO of Ethiopian Construction Works Corporation (ECWC) demonstrated strong interest in collaborating with the team for the adoption of the ACI Code and so an International Partner Agreement was signed.

As a result of ACI revising and adjusting its strategy for Africa, ACI continued to struggle to gain traction to move its project forward. Although it believes that the lessons learned, established working relationships, and solidified activities can help yield more tangible outcomes and benefits for beneficiaries in Africa in the future, ACI does not intend to propose a new subaward, but plans to share a final report with ANSI highlighting the outcomes of this sub-award activity to close out its activities in the region.

# INDO-PACIFIC

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

### Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

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

PT IAPMO Group hit an important milestone this quarter. Its faucet testing laboratory now has full capabilities to test to SNI 122:2022.

Currently, SNI 122:2022 is considered a voluntary standard. Until it is made mandatory by a ministry, PT IAPMO Group Indonesia is seeking to be appointed as the Product Certification Body recognized by BSN. IAPMO is currently in discussion with Indonesian manufacturers interested in certification to SNI 122:2022 in order to initiate that formal process.

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

USAID is undergoing internal review processes of the concurrence memo to secure concurrence from the Philippines Mission.

Activity #7.3 - Develop a Standards Action Plan identifying international product standards that will establish baseline and "reach" efficiency standards for plumbing products in the Philippines technical regulations

USAID is undergoing internal review processes of the concurrence memo to secure concurrence from the Philippines Mission.

Activity #7.4 – Conduct review of the Philippines legal requirements for the import and conformity assessment of plumbing products

USAID is undergoing internal review processes of the concurrence memo to secure concurrence from the Philippines Mission.

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

Partner country: India

The activity has been completed, and final progress has been reported under the Q4 2022 report.

# 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

The activity has been completed, and final progress has been reported under the Q4 2022 report. Moreover, this subaward has closed at the end of the Q1 2023 reporting period and as such the team will be sharing a final report on the activity with ANSI and USAID in the near future.

# MIDDLE EAST NORTH AFRICA

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

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

Partner country: Morocco

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

As mentioned in the Q4 2022 report, NSF and the Moroccan Ministry of Health (MoH) entered a formal partnership for the SA2 project implementation in Morocco as it was identified to be a good tie-in to the Morocco National Water Committee's initiatives and efforts. All stakeholders/members of the National Water Committee took part in the training. Participation from these National Water Committee members offered opportunity to have clear input from all of -members on how they envision the best way of moving forward toward adopting or referencing NSF/ANSI/CAN Standards.

As follow-up to the Morocco trainings, Q1 2023 efforts consisted primarily of Wessam Jihad, Principal – Water for Middle East, maintaining contact with Rachid Wahabi of the MoH – Morocco to stay updated on the National Water Committee discussions and provide support to their discussion and initiatives, as needed. As a result, two virtual meetings with MoH – Morocco's Rachid Wahabi, Chief of Environmental Health Division, occurred.

The first follow-up virtual meeting with the Morocco MoH (Rachid Wahabi) took place in January 2023. During this meeting, Mr. Wahabi confirmed that National Water Committee discussions are yet on-going, and Mr. Wahabi requested examples of NSF/ANS Standards 60 and 61 test reports that could be

presented to the Committee. Wessam collaborated with NSF's Senior Director of Commercial Water, Theresa Bellish, to provide the requested reports.

The second follow up meeting with Mr. Wahabi of MoH – Morocco was in early March 2023. During this meeting, it was again confirmed that the National Water Committee's conversations/efforts are yet active, with the following added detail:

- The value of standards and conformity assessment conveyed during the trainings was well received. However, the National Water Committee, during their discussion, identified it to be difficult to transition from current approval schemes that use the ACS (the French scheme) or WRAS (the UK scheme) to an American scheme with NSF. To implement a full NSF certification scheme, a transition plan needs to be implemented.

- The National Water Committee will need to discuss the most optimum way for implementation/adoption in the future. Moreover, in NSF 60 there are criteria levels may require strengthened laboratory capabilities for the testing methods. Technical capacity strengthening would be an investment decision and would take time to implement. Concurrently to the NSF trainings, the National Water Committee was already working to develop drinking water standards to govern the activities of producers and distributors of drinking water products and materials. As such, the National Water Committee welcomed the trainings on NSF standards 60 & 61 as an added value to their current activities.

The idea to reference NSF/ANSI Standards 60 and 61 standards as one of the accepted requirements among others is being considered. With this, the MoH – Morocco requested to share example of other guidelines from the region where NSF certificate is accepted to help visualize how this can be drafted in the local documents.

This subaward closed at the end of the Q1 2023 reporting period and as such the team will be sharing a final report on the activity with ANSI and USAID in the near future, highlighting post implementation outcomes to be expected as well.

## 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

Activity #11.5 – Specialist training programs for Ghana Ministry of Health, Ghana Ministry of Trade and Industry, Ghana FDA and GSA on quality requirements and procuring PPE (August 2021)

Implementation has been finalized after facing many delays. Ethical Apparel has passed the qualification

testing for the surgical face masks they were trying to produce in Ghana. As a result, Ethical Apparel's surgical masks now meet the ASTM Level 2 Standard, and can now be produced in Ghana.

The next step is then for a Quality Management System (QMS) EEA to be developed. GSA needs to approve the QMS, get training on how to conduct it and the Ministry of Health will need to place orders for EEA to build the clean room and start producing the masks. This will tentatively take place under a post implementation phase of the project.

# 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

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 Coalition continued advancing MDRC objectives in its leadership of an International Center for Emergency Regulatory Response (ICERR) in the form of a dedicated COVID-19 Medical Device workstream of the GMTA/GDA. This workstream was approved in principle in 2020-2021 and formally constituted by the GMTA Regulatory Committee in September 2021. The Coalition continued efforts to support GMTA in the:

- Development of COVID-19 recommendations to IMDRF, WHO, G/AHWP regarding appropriate international benchmarks;
- Coordination towards an MDRC-related training to address pandemic/emergency elements; and
- Eventual inclusion of links to the MDRC project website and any related resources on the GMTA website.

As part of these efforts, AdvaMed staffs the GMTA Regulatory Working Group, driving MDRC objectives alongside partners from the Coalition, AdvaMed, MedTech Europe, Mecomed, private companies, and standard developing organizations.

Activity #12.2 – The Coalition will promote, ensure, measure, and report the engagement of women throughout the implementation of the project in all geographies. (Q3 2021 – Q2 2022)

In all project activities, including trainings, MDRC tracks the participants and their gender identification, when reported. A breakdown of the engagement of women under this activity will be detailed further down in this report.

#### Africa

Activity #12.6 – Tier One and Two Regional Meetings/Trainings (Timing is subject to the issuance of concurrence by the USAID Mission to Kenya. Preliminary dates are included below and are subject to change.)

**Regional**

In Q1 2023, in cooperation with the African Medical Device Forum (AMDF) MDRC organized a two-day Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector in Africa. The workshop advanced both Tier One and Two workstreams in all three African Project countries. On the workshop's first day, the focus was on Tier One, and participants included16 government stakeholders including MDRC countries Kenya, South Africa, and Ghana but also AMDF members such as Ethiopia, Tanzania, and Zimbabwe. The workshop convened a total of 165 attendees, 111 of which were from the private sector. The second day focused on Tier Two, MDRC convened 104 attendees, 67 of which were from the private sector.

**Ghana**

MDRC accelerated its Ghana workstream engagement in the structuring of the MDRC Africa Liaison position pending approval of the revised budget.

**Kenya**

Under this reporting period the team held in-person internal training sessions for the MDRC team based in the region, as well as key meetings which included:

- Coordination session with the CEO and staff of the Kenya Pharmacy and Poisons Board (PPB). Attendees confirmed the 2023 workplan, including training dates and agendas and focusing on an overhaul of the Kenyan medical device regulatory framework implementing GRP, reliance models, and the use of international standards. The meeting also confirmed the desired parameters of the MDRC Africa Liaison and metrics. MDRC also leveraged the opportunity to engage with the PPB chair of the AMDF on regional training.
- Session with KEBS, including the Kenyan representative to the WTO TBT Committee and leads for standards, conformity assessment and metrology. The meeting focused on details of a pathway to exempt medtech market access from the KEBS redundant Pre-Export Verification of Conformity (PVoC) regime and possible incorporation of GRP and USMCA Medical Device Annex type commitments in the ongoing Strategic Trade and Investment Partnership (STIP).
- Session with ARSO, confirming their engagement in the MDRC Africa workstreams and Africa GRP Workshop.
- Session with MEDAK, the local industry association for medical technologies. This meeting included participation from BBraun, Medtronic, Roche and local medtech companies. Discussions centered on engagement in MDRC workstreams and ramping up participation in international medtech standardization.
- Additional meetings with the Kenya National Chamber of Commerce and Industry, the AmCham Kenya, USAID Mission, and FCS.
- Interviews with pre-candidates for the MDRC Africa Liaison position.

Throughout Q1, MDRC met with FDA/CDRH to discuss Africa Capacity Building. The team also shared an updated proposal for U.S. FDA to consider. It was also proposed for the U.S. FDA to develop a position paper regarding basic principles for MTAPs. MDRC outlined its concerns with the WHO GBT+

assessment and shared their work to provide direct support to Kenya through Africa Liaisons. During a later meeting, FDA/CDRH and MDRC discussed trainings and capacity building, noting a lack of alignment of PPB-expressed scope for the MRDC training agenda. They agreed to reconvene jointly with PPB to confirm details and schedule a joint coordination call among PPB, USFDA, and MDRC.

**South Africa**

On February 2, 2023 SAHPRA and MDRC finalized all signatures on the Terms of Reference (TOR), which formalized their partnership in executing Tier One and Two workstreams. With the TOR fully executed, MDRC could deepen its capacity building efforts in the project country.

**Indo-Pacific**

Activity #12.10 – Tier Two Regional Meetings/Trainings

In early March 2023, the team collaborated with ASEAN to hold a virtual Regional Workshop on Good Regulatory Practices (GRPs) and Medical Devices Regulation. The workshop featured discussions on the World Trade Organization's Technical Barriers to Trade Agreement and legal obligations as it relates to GRPs and national commitments, assessment of safety and performance of medical devices; regulatory reliance models for medical device assessment; and post-market surveillance.

Moreover, following a session held in December 2022, the second Small Group Session with Indonesian MOH officials was held on February 6 and 7, 2023. Approximately 20 officials attended the two-day session, which focused on conformity assessment and personalized medical devices. The latter topic was included at MOH's request. The MDRC team also introduced the conformity assessment checklist and offered to work with officials on tailoring it to their needs. As part of preparations for the second Small Group Session, the MDRC had a coordination call with speakers to align on its objectives and agenda. MDRC also separately met the FDA to discuss its participation at the Session, and the virtual regional workshop.

The MDRC is currently seeking to socialize the GRP and conformity assessment checklists with the Indonesian Ministry of Health. The team had a check in call with local experts and members of the ministry team on March 24, 2023 and will work together to develop an activity plan (including socializing of the checklists) in the coming weeks.

**Latin America**

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

In February, 2023, MDRC agreed to produce a detailed analysis on specific areas of interest to address misalignment on ISO 13485 and the Medical Device Single Audit Program (MDSAP).

In March, 2023, the team presented on GRP and Regulatory Systems Strengthening at the Drug Information (DIA) Latin American Annual Meeting, and met with BD to address regulatory barriers, presented at the Strategic Meeting with Infarvet y Dispositivos Médicos (CANIFARMA). MDRC also

discussed with the Latin American Federation of the Pharmaceutical Industry (FIFARMA) on GRP implementation. MDRC shared checklists and SOPs developed for GRP implementation and mentioned the intention of the National Planning Department of Colombia (DNP) to implement GRP at a national and territorial level for all regulated sectors. Discussions focused on challenges faced by NRAs in implementing GRP, industry actions to support governments, maturity level challenges hindering GRP implementation, practical application of GRP principles, and benefits of open public consultations.

Activity #12.14 – Hire a dedicated MDRC Liaison to facilitate and coordinate the implementation of MEL Plan objectives in Colombia

MDRC's Colombia Liaison rapidly advanced project objectives in the country. The Liaison convened 50 meetings with local Tier One and Two government stakeholders. Among additional workstreams to build regulatory capacity and ensure compliance with international obligations, the Liaison continued to coordinate the following alongside the Ministry of Health, INVIMA, DNP, and others:

- Ex-ante evaluation for clinical research
- Ex-post evaluations of Decrees 4725 and 3770
- Ex-ante evaluations of Decrees 4725 and 3770
- Ex-ante evaluation for regulation pertaining to EUAs
- Ex-ante evaluation for Good Regulatory Practices

MDRC through the Liaison led the formal implementation and institutionalization of GRP in Colombia at both Tiers One and Two. At Tier Two, the Ministry of Health formally approved and published GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. MDRC will began formal trainings on GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents those requirements alongside the Ministry in Q1 2023. These requirements were formally approved and published during Q4 2022. At Tier One, MDRC continued engagements with the National Planning Department (DNP), which has recognized the work of the Ministry of Health and MDRC in a national contest on GRP Implementation.

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

**Brazil**

In Brazil, MDRC had meetings with Brazilian National Standards Organization (ABNT) Technical Committee CB-36, National Institute of Metrology Standardization and Industrial Quality (INMETRO), and Brazilian Health Regulatory Agency (ANVISA) to discuss ongoing workstreams. The meetings focused on topics such as ISO 15197-2013, blood glucose monitoring systems, and restructuring within the Scheme Support project. INMETRO provided updates on their new government structure and presented their three pillars of capacity building, consultancy, and restructuring. MDRC proposed joint meetings with the Regulatory Policies Secretary and INMETRO to present the GRP checklists. INMETRO scheduled a meeting with ANVISA to explore opportunities for coordination and requested MDRC's assistance on defining benefits and benchmarking countries with similar systems.

**Colombia**

In Q1 2023, MDRC continued to lead the formal implementation and institutionalization of GRP in Colombia at both Tiers One and Two, with a focus on formal training on GRP requirements. This comes

as a result of constant coordination and on-the-ground work by the Colombia Liaison and broader MDRC team. The Ministry of Health was formally recognized in a national contest for its approval and publication GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents.

*Processes and procedures*
Throughout Q1 2023, MDRC has conducted meetings with the Ministry of Health (MoH) and Colombia National Food and Drug Surveillance Institute (INVIMA) to present the results of the MDRC project and discuss adding additional personnel to assist in the process. MDRC has also been coordinating with the MoH to develop a training agenda for March and April focused on the stages of procedures, problem tree design, and advancing harmonization. In collaboration with the MoH, MDRC developed a training video. A legal meeting of the health sector was also held in February 2023 to outline the next steps regarding the trainings, and the legal office recognized MDRC for its support and extended the invitation to the entire health sector.

*Ex-Ante Evaluation for Clinical Research*
The summary describes the Ex-Ante evaluation process for clinical research. MDRC met with the MoH and INVIMA several times to review the problem tree, schedule, and identify alternatives to solve the identified issues. MDRC also presented the problem tree and introduced GRPs to stakeholders. Meetings were held to advance the structure of the final RIA document, with emphasis on evaluating objective 4 for international harmonization. MDRC estimated that the ex-ante evaluation process was about 34% complete as of their last meeting with the MoH and INVIMA.

*Ex-Post Evaluations of Decrees 4725 and 3770*
The ex-post evaluations of decrees 4725 and 3770 involved meetings between MDRC, MoH, and INVIMA to discuss proposed responses to stakeholder comments and to finalize evaluation documents. Attendees also discussed next steps in the evaluation process, including the application of a matrix to evaluate objective 6 of the problem tree related to managing information on Medical Devices and In Vitro Diagnostic Reagents. MDRC recommended and agreed to advance the general evaluation document. As of the final meeting on 14 February, MDRC estimated that the ex-post evaluation process was about 84% completed.

*Ex-Ante Evaluations of Decrees 4725 and 3770*
The ex-ante evaluation process for decrees 4725 and 3770 involved several meetings between MDRC, MoH, and INVIMA. As of January 25, the process was estimated to be about 9% completed. Throughout February and March, the groups continued to work on the document supporting the problem tree and presented comments and proposed recommendations for implementation. As of March 8, the ex-ante evaluation process was estimated to be about 10% complete.

*Ex-Ante Evaluation for Good Manufacturing Processes*
In the ex-ante evaluation for good manufacturing processes, on January 23, MDRC discussed with the MoH and INVIMA the identification of variables to assess the benefits and risks of problem tree alternatives. MoH proposed a simplified data collection process due to limited capacity, but MDRC emphasized the importance of quantitative data. An expert analysis would be carried out, and ANDI and FENALCO would be invited to participate. INVIMA would share alternatives with MoH to develop a new tool to choose the best alternative, and MoH agreed to have internal meetings with INVIMA. As of this meeting, MDRC estimated that the ex-ante evaluation process was about 40% completed.

*Ex-Ante Evaluation for Emergency Use Authorization (EUA)*
The ex-ante evaluation process for emergency use authorization involved meetings between MDRC, MoH, and INVIMA to review progress on identifying alternatives that could achieve the defined objectives in the problem tree. On 31 January, progress was presented on two potential alternatives, and an agreement would be finalized after an analysis of their legal feasibility. At that point, MDRC estimated that the ex-ante evaluation process was about 30% completed.

*TBT interpretation*
MDRC met with the Ministry of Health, INVIMA, and the Ministry of Commerce to discuss technical regulations and the sanitary registry's status as one. The Ministry of Commerce suggested using international standards, and the MoH had questions about the registry. They agreed to clarify the scope of technical regulations and to continue discussing the status of the sanitary registry at a later meeting.

*General*
The team continued its close engagement with the MoH throughout the reporting period and provided legal analysis regarding the application of several decrees. The analysis revealed that the MoH is required to begin the Regulatory Impact Analysis process, which has already been initiated. The analysis must be completed before the new regulation can be implemented, contrary to the previous belief that the deadline for regulation was December 2023.

**Mexico**

During Q1, MDRC and the Mexican Federal Commission for the Protection of Sanitary Risk (COFEPRIS) also discussed the draft document on Regulatory Certainty for Medical Devices which contains regulatory initiatives internal to COFEPRIS, such as their commitment to the Medical Device Single Audit Program (MDSAP). Attendees discussed NOM-241 and NOM-137 (Labeling and Stability Studies). COFEPRIS advised that internal discussions were ongoing for NOM-241, NOM-173, and the implementation of the Checklists for GRP. The possibility of collaboration with NRAs such as ANVISA was also discussed, but there were no outstanding advances on the metrics.

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MDRC concluded its Q1 Mexico engagements by holding multiple meetings with MDRC partners in Mexico City, including the participation in the V Annual Forum on Medical Devices – Innovation by Definition, organized by AMID and CANIFARMA, which convened COFEPRIS, FEUM and private sector representatives.

**Peru**

The team plans to engage with Peru's newly appointed Under-Secretary of Simplification and Regulatory Analysis to introduce the project and follow up on the triannual review of the administrative procedures at DIGIMED.

## 2.4 Implementation Challenges

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

The final webinar with ARSO went smoothly with a lot of interaction from both the public and private sector present to learn more about biofuel standardization, however the momentum from there has been a bit slow regarding the New Work Item Proposal. Pivot will continue to communicate with ARSO and ANSI in regard to next steps for approval and budgeting requirements.

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

Delays in obtaining the required J-1 Visas necessary for the West African participants is still proving problematic for the U.S. Study Tour. At the time of reporting 6 out of the 8 focal points have received their visa to attend the Denver meetings. Both focal points from Cote D'Ivoire are still in the process of obtaining their visa. One of them is expected to have the visa by May 19, 2023; the second focal point started the process later as they replaced a previous person, but the expectation is that they will have their visa before the event as well.

## Activity #7 – Increase the Flow of WASH Services

Local manufacturers are hesitant about making a mandatory standard for faucets. IAPMO is working to educate these manufacturers about the role of this new standard in ensuring the safety and performance of their products as well in making their products more competitive in the global market.

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

### Government Mobilization

### Ghana

As stated in the Q4 2022 report, MDRC experienced continued delays in engagement with governmental stakeholders. One major challenge is the technical capacity of those government officials. For example, officials do not always accept correspondence from external emails, which makes scheduling very difficult. In response, MDRC conducted additional outreach via WhatsApp and through U.S. Embassy Officials. Despite that outreach, MDRC still experienced difficulty scheduling engagements in Ghana.

MDRC is still pushing for the conclusion of MOUs in Q1-Q2 2023, however the team recognizes the late timeframe for fully developing workstreams in the country. Moving forward, MDRC will continue to invite Ghanaian government and local partners to participate in relevant continental capacity building as appropriate.

### Mexico

In Q1 2023, MDRC experienced difficulties in making progress with its workstreams with COFEPRIS. There were delays in the review process of the GRP Checklist due to organizational changes in FEUM, and MDRC facilitated a meeting between COFEPRIS and USAID to reinforce the Federal Commissioner's commitment and support for the project. MDRC sought to increase frequency of its meetings with COFEPRIS and discussions in Q1 2023 were focused on NOM-241 to address concerns about bottlenecks and technical barriers to trade. COFEPRIS plans to issue a circular for NOM-241, and developed a

document titled "Estrategia de Certidumbre Regulatoria para Dispositivos Médicos" which includes the creation of a Committee on Good Regulatory Practices. When requested, MDRC will offer input to documents and will continue to offer technical assistance related to implement international benchmarks and avoid TBTs.

**WHO MedTech Guidance**

As noted, MDRC continues to include the WHO and its international benchmark guidance for Medical Device National Regulatory Authorities (MD NRAs) in programming with project country NRAs. However, MDRC believes that a number of systemic WHO practices work at cross-purposes with both MDRC's efforts to build NRA capacity as well as guidance developed by the IMDRF, FDA/CDRH, WTO and the WHO.
As MDRC continues its work, those practices may hinder MDRC's ability to fully realize its project objectives, namely those that do not align with GRPs.

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**Coordination on Aid for MD NRA Capacity Building**

From the project's inception, MDRC has worked to coordinate with USAID, FDA/CDRH and other USAID project teams to ensure an aligned and non-duplicative approach to capacity building. Through the establishment of a coordination team, all parties have worked to share information and ensure proper differentiation between medtech and medicines in their project workstreams. MDRC believes that improving the information sharing mechanisms between all parties, including with projects funded by other Agencies, will be critical to future successful capacity building.

# 3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

| Activity # | Sub activity # | Country | Meeting/ Event | Date | Participants |
|---|---|---|---|---|---|
| 1 | N/A | ARSO | ARSO Webinars on Bioethanol | February 24, 2023 | 70 participants |
| 5 | 5.7 | West Africa | Workshop on Petroleum Harmonization | March 20-22, 2023 | Total: 28 (8 private sector, and 9 Women) |

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|---|---|---|---|---|---|
| /8 | 8.3 | Africa | Workshop 2 on G400 – Utility Management System and G200 – Distribution Systems Operation And Management | January 10, 11, 2023 | 40 attendees including 12 different private sector organizations present |
| 12 | 12.05 | Africa | Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector in Africa | January 3, 2023 | 269 attendees<br>188 female, 81 male<br>(178 private sector) |
| 12 | 12.10 | South East Asia | ASEAN Workshop on Good Regulatory Practices and Medical Device Regulation | February 28, 2023 | 414 attendees<br>294 female, 120 male<br>(228 private sector) |
| 12 | 12.10 | Indonesia | Workshop: Small Group Discussion on GRP and QMS | February 6-7, 2023 | 42 attendees<br>26 female, 16 male<br>(5 private sector) |
| 12 | 12.14 | Colombia | Workshop: Small Group Discussion on GRP and QMS | March 24, 2023 | 42 attendees<br>26 female, 16 male<br>(5 private sector) |

# 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 **4** trainings to report which is one less from the total number of training targeted. A breakdown of the different workshops is presented below by activity.[1]

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

Under this activity there was **1** webinar that was targeted by the subawards to take place under this reporting period to continue to advance the implementation of the project. For this quarter the team was

[1] Activities not mentioned under this section did not select it for their implementation.

able reach this target. This is due to the new agreement between ANSI and ARSO to organize a webinar series on bioethanol as a result of the strong buy in in the region to gain more expertise on Renewable Fuels overall, which pushed for the implementation of a webinar in partnership with ARSO in February 2023.

For the upcoming quarter the team has set a target of **0**.

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

The target for this activity was to hold **1** training event during this reporting quarter. With the organization of the Workshop in March in Senegal this target was indeed reached.

The last in person event is set for June in Denver for the focal points to take a US Study Tour and participate in the ASTM Committee meeting. The target for the upcoming quarter is then **1**.

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

In Q1 2023, AWWA set a target of **2** for Africa and **0** for India. As the final workshop for this activity in Africa is now taking place in person in Zambia in April 2023, only one of the workshops targeted for this period took place. However, despite having one less training this quarter, the demand to have the final training in person next quarter actually demonstrates a very strong buy in from local stakeholders and the ability for the activity to have a greater impact in person in the next quarter.

As such, for Q2 2023, AWWA sets a target of **1** for Africa and **0** for India.

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

For Q1 2023, MDRC set a target of **1** workshop under this indicator which it reached.

For Q2 2023, MDRC sets a target of **1** workshop under this indicator.

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

Under this reporting period for this performance indicator there were a total of **4** workshops to report cumulating to a total of **552** participants, which is greater than the targeted participants set at **118**. This is explained by the strong engagement in many of the activities below. Indeed, most are not the first workshop of the activity, and so they are building on the success of the previous trainings to increase their reach. A breakdown of the different participants in said workshops is presented below by activity.[2]

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

[2] *Idem*

## Renewable Fuels Workshops

Under this activity the target was to reach a minimum of **20** participants in the training to raise awareness around TBT principles. This target was exceeded as the Webinars with ARSO had **70** attendees.

For the upcoming quarter the team has set a target of **20**.

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

The target under this indicator was set at **20** for this quarter. Given that the team was able to host a workshop in Senegal it was able to exceed this target hosting **28** participants demonstrating the strong involvement from both public and private sector in the region to facilitate cross border trade.

As the next event is a study tour in the US for the focal points the team sets the target for Q2 2023 at **8**.

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

In Q1 2023, AWWA set a target of **28** for Africa and **0** for India. The target for Africa was surpassed as **40** participants joined the workshop.

For the upcoming quarter, AWWA sets a target of **0** for India and **30** for Africa.

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

Given workshops were implemented in the past reporting quarter, NSF set for the first quarter of 2023 a target of **0** events in both countries, as this quarter focused on implementing the lessons from the trainings that were just rolled out, particularly in Morocco as noted earlier in the report.

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

For Q1 2023, the team executed 1 Workshop on Good Regulatory Practices and Medical Device Regulation.
The workshop attracted **225** participants on Day 1 and **189** participants on Day 2, which exceeded the target number of 50. This workshop is essential to building good regulatory capacities and addressing barriers to trade by:

- Reviewing the World Trade Organization's (WTO) Technical Barriers to Trade (TBT) agreement and legal obligations as it relates to GRPs and national commitments;
- Discussing regulatory reliance models for medical device assessment;
- Emphasizing the role of GRP in recovery from COVID-19 and reducing barriers to trade; and
- Facilitating long-term GRP collaboration among the project countries.

For Q2 2023, MDRC sets a target of **75** participants under this indicator.

# 5. LESSONS LEARNED

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

Throughout the engagement in Morocco, NSF learned that support from a government ministry was vital to NSF's success with their trainings. The Ministry of Health supported WASH stakeholder outreach and distributed invitations, including to the members of the Moroccan National Water Committee. The MoH also provided the venue for the two-day training. Furthermore, MoH's collaboration has been instrumental in NSF being updated on the National Water Committee's conversations and with bringing forward NSF/ANSI resources to the national committee. NSF looks forward to continued engagement with the MoH beyond the conclusion of this project.

Additionally, NSF was reminded that progress takes time. The National Water Committee of Morocco is active and making progress, however the path forward was not fully settled by the end of 2022, as targeted; and follow ups had to take place during this current reporting period.

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

The project team continues to incorporate lessons learned on hybrid in-person/virtual engagements with stakeholders. Learning from the execution of the events alongside the June 2022 Summit of the Americas, MDRC organized both virtual and in-person trainings in Q1 2023.

The project team continues to utilize its online capacity-building and digital resource capabilities to extend programming to a large virtual audience. While in-person training is extremely effective, most participants of MDRC trainings remain virtual. MDRC's virtual platform and Zoom licenses are critical to reaching those participants and offering simultaneous language interpretation for both in-person and virtual attendees. These learnings are increasingly critical in the effective execution of capacity building.

# 6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

| Activity # | Sub activity # | Country | Publications/ Reports | Meeting/ Event | Date | Location | USAID participation |
|---|---|---|---|---|---|---|---|
| 5 | 5.5 | West Africa | N/A | US study tour and participation in the ASTM Committee D02 meetings | 24-29 June, 2023 | Denver, CO | Yes |
| 12 | 12.6 | Africa | N/A | Training sessions with medical device NRAs utilizing a curriculum developed by FDA | May/June | Hybrid | Yes |

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