



Standards Alliance: Phase 2

Quarterly Report

Q4 October 1st - December 31st 2022

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Table of Contents

1. PROGRAM OVERVIEW/SUMMARY.....	2
2. ACTIVITY IMPLEMENTATION PROGRESS.....	3
3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT.....	19
4. RESULTS ACHIEVED.....	21
5. LESSONS LEARNED.....	24
6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS.....	25

I. PROGRAM OVERVIEW/SUMMARY

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:	Q4 October 1 st - December 31 st 2022

I.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 fourth quarter of 2022 continued with the implementation of all activities under the approved subawards. The MDRC program in particular continued to make progress this quarter, holding an in-person workshop alongside the MedTech Conference in Boston in October 2022. This event furthered the work for the implementation of GRP for the Medical Devices sector, helping increase safety and health in the partner countries. Additionally, good progress was also made in water and sanitation activities in India and North Africa with several key workshops held in the regions, helping the promotion of water safety standards. Finally, ANSI continued to monitor the COVID-19 pandemic throughout Q4 and is adjusting in person training plans for a better activity implementation, as restrictions continue to ease up.

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 team built on the virtual 2-day bioethanol standardization workshop which was held in Mali on September 13-14, 2022. 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, adjacent sector impacts, the importance of smart policy and standards, and implementation of bioethanol businesses. Expert speakers presented on each topic, and there was a question and answer session after each presentation.

Thanks to this event, valuable connections between local stakeholders and speakers, including ANSI, U.S. Grains Council, and ASTM have continued to expand in October 2022. During this reporting period the team met in person with constituents from Mali at CCF in Ghana to discuss further partnership and made an introduction between AMANORM (the Mali national standards body) and ASTM. Moreover, the team continued key dialogues with Togo's government stakeholders (Ministry of Energy, MDEM, ATN, etc) to further bioethanol standardization in that country.

Additionally, in partnership with ARSO, a Standards and Quality Control (QC) webinar was organized in November 2022. 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. Expert speakers were recruited for this webinar and a similar collaboration will occur in the first quarter of 2023; as these issues have become a grave international concern and are linked to the United Nations' Sustainable Development Goals (SDGs). Transitioning to clean cooking with bioethanol specifically targets six SDGs: No Poverty (1), Good Health and Well-Being (3), Gender Equality (5), Affordable and Clean Energy (7), Decent Work and Economic Growth (8), and Life on Land (15).

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 that will take place in Q1 2023 on Good Manufacturing Practices for Cosmetics; which follows the last webinar in May 2022. For this webinar, experts from PCPC will continue to underline the importance of Good Manufacturing Practices for cosmetics in ensuring consistent quality. Speakers will expand upon the ISO

standard for cosmetics GMP and provided top-level insight into aspects of practical implementation. The objective of the overall series has been to ensure 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.

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

During Q4, the CWSC began fieldwork interviews. The CWSC reached out to a wide array of stakeholders in the three target countries starting in late November and were able to conduct eight (8) interviews. There are several people with whom the CWSC will follow-up in Q1 2023 (i.e., those stakeholders who did not respond to their emails in Q4) in order to complete the fieldwork.

Once the interviews are completed, the relevant findings and information from the interviews will be incorporated within the country reports. The CWSC also started reviewing the notes from the interviews conducted. As a result of that review, the CWSC has followed-up with additional questions for two of the interviewees. The CWSC will need to review the responses from the interviewees in Q1 2023. Please refer to Q3 2022 report for a list of all interviewees.

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

The CWSC has started drafting each country report. As the interviews will not have been completed yet, the first comprehensive draft country reports will be based on the deskwork findings alone. The CWSC has almost completed a first draft of the country reports based on the deskwork findings by the end of January and should share those with IAPMO for their review and comment.

The CWSC expects that IAPMO will have significant insight on some of the topics discussed within the country reports, and that their review will provide additional insight in areas to be explored. The CWSC will also discuss with IAPMO the arrangement of the education and engagement workshops, which are expected to be initiated in Q2 2023.

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

Partner countries Lesotho, Malawi, and Zambia

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

Activity completed and training material used for the first virtual training in Q3 2022. Based on lessons learned from the India workshops, the order of standards addressed has been adjusted for the Africa workshops, and additional interactivity will be added to the agenda.

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

As reported in Q3, the first virtual workshop for the Africa trainings was held on September 7th and 8th for 3 hours each day. Over 40 individuals from Africa participated in the first workshop. Follow-up monthly check-in calls were held on October 12th and November 15th. 25 individuals attended the October call and 34 attended the November call. The second virtual workshop is scheduled for January 10th and 11th with 3 to 3-1/2 hours scheduled for each day. Monthly check-in calls are scheduled on February 7th, and in March (date TBD), with a third and final workshop scheduled in-person for April 25th and 26th in Livingstone, Zambia.

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 two key meetings with regional and national SDOs to discuss further trainings.

ASTM's technical consultant's presentation during a webinar hosted by ARSO on October 25, 2022 (although unplanned under the Standards Alliance project) provided an opportunity to share the success of the current ASTM/API harmonization of petroleum standards under the West Africa activity.

On November 8, the project leader and the ANSI project manager met with the Director of the Senegalese Standards Body (ASN) at the ANSI Offices in Washington D.C. to discuss the progress of the project and plan for the next Africa Workshop to be held in Senegal in early 2023. Subsequent to that meeting, the dates for the next Africa-based workshop have been secured for March 20-22, 2023 in Dakar, Senegal. Both public and private stakeholders from Senegal will participate and the training will include a visit to the Société Africaine de Raffinage (SAR) or African Refining Company while in the country. .

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

During Q4, much time was spent planning the logistics to hold a Study Tour in the U.S. which was to be held on the sidelines of the meetings of ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants in Florida and in Washington D.C. in December 2022.

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. The Study Tour is now scheduled to take place at ASTM's next scheduled committee meeting on the petroleum topic 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: Continent Wide (Tentatively)

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 strategy has been put on hold due to the previously reported challenges with implementation in Kenya, Uganda, and Tanzania, resulting in the need to create, develop and receive approval of a revised strategy. However, it is not ready for full implementation under the Standards Alliance, and thus it has not received full approval yet. As a result of this support, ACI is continuing to revise and adjust its strategy for Africa, and expects to finalize their proposal in February 2023.

During this reporting period, ACI took the following steps to develop this new strategy so that it can be ready for implementation in Q1 2023:

- **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. In addition, FAEO is holding the “2023 FAEO Engineering Policy and Presidential Inauguration Conference” on January 27, 2022 in Kigali, Rwanda, which will be a great opportunity to meet with many of the engineering associations in Africa, to determine where there is interest in utilizing ACI’s concrete knowledge to improve the quality of concrete construction. An Africa Mission to pursue this opportunity was developed, and while mainly focused on Kigali, Rwanda, it also involves travel to Djibouti, Ethiopia and South Africa to meet with current ACI partners to further develop their respective programs. Also, a special effort was made to contact the East African countries the team had already been working with (Kenya, Tanzania, Uganda), and it will be meeting with the Uganda Institution of Professional Engineers (UIPE) and the Institution of Engineers of Kenya (IEK) during the FAEO event to determine if there is a suitable level of interest in continuing and further developing the relationship between the organizations.
- **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.

The signing of these four IPA's, in addition to the four signed previously, give ACI a good base of organizations to work with for future development, while still building the network during meetings in Kigali in January 2023. They will be a key part of the revised strategy for Africa.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services (Also appears in Middle East North Africa section)

Partner countries: Indonesia

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

SNI 122:2022 was recognized by the National Standardization of Agency of Indonesia (BSN) by the Head of BSN Decree No. 213/KEP/BSN/7/2022 on July 18 , 2022.

In Q4, IAPMO has been working to register SNI 122:2022 with the Indonesian National Accreditation Committee (KAN) to formalize the authorized testing scope for the new standard. IAPMO anticipates that this will be finalized in their next round of reviews; the date is still to be determined.

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

IAPMO received congressional approval to work in the Philippines in Q4 2022. USAID is undergoing internal review processes of the concurrence memo before outreach to the Philippines Mission can commence.

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

IAPMO received congressional approval to work in the Philippines in Q4 2022. USAID is undergoing internal review processes of the concurrence memo before outreach to the Philippines Mission can commence.

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

IAPMO received congressional approval to work in the Philippines in Q4 2022. USAID is undergoing internal review processes of the concurrence memo before outreach to the Philippines Mission can commence.

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

Partner country: India

Activity #8.3 – Conduct training with participants from 15+ Indian water utilities in Mumbai and Hyderabad

This quarter AWWA completed delivery of the third workshop (held virtually on October 18). The virtual workshop lasted approximately 3-1/2 hours and was attended by 15 participants from 7 Indian water and wastewater utilities. All registered participants were provided with a pdf version of the fifth ANSI/AWWA Standards covered in the workshop series (G5100 – Wastewater Treatment Plant Operation and Management). A follow-up monthly check-in call was held on November 9, lasting approximately 1-1/2 hours, and provided participants an opportunity to have their homework items checked and to have any questions answered.

The fourth and final workshop was held in-person in Varanasi, India, on December 5-6 and included 17 participants from 10 utilities. The workshop was held in conjunction with AWWA India's annual conference, which hosted over 300 water professionals from across the public and private sector in India. Participants of the workshop were able to access the AWWA India conference. AWWA and ANSI's primary contact at the USAID Mission in India, RK Srinivasan, attended the workshop and conference.

AWWA's planned activities for India as part of the grant have concluded. AWWA does plan to maintain contact with the participants to encourage continued use of the standards, maintain an India based user group for the Utility Management Standards, and to garner feedback on the successes and challenges that utilities experience in their ongoing implementation of the management practices.

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

During this reporting period NSF's team in Brazil continued to receive and respond to the questions generated by the NSF/ANSI/CAN Standard 61 and NSF/ANSI/CAN Standard 60 webinars. Questions this quarter were primarily received from equipment manufacturers and water treatment companies (Utilities Plants).

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

The NSF/ANSI Standard 60 training, pre-recorded, was played live on October 25, 2022 using platform ON24 (<https://www.on24.com/>). The event was delivered in Portuguese and included a live Question and Answer period, also conducted in Portuguese.

Registration for the training was open and free of charge to all interested in attending. A registration link was sent to the list of stakeholders with whom NSF had indicated in the previous quarterly report, so that awareness around the event could remain high. Further, news of the training was broadly advertised on NSF's media the week of October 3, shared with ANSI who disseminated the notification of the training via their channels and with USAID via ANSI to share the notification of the training via their channels.

Related to the responses for the webinar, there were 106 registrations in total. From those who registered, 52 attended the webinar live, which is approximately a 49% attendance from registrations; of those who attended the retention rate throughout the webinar was strong, with an average of 51 minutes watched by attendees.

All who registered were automatically sent the on-demand webinar to view at their leisure following the event and webinar is posted on NSF Brazil website located at . <https://nsfinternational.com.br/webinar-nsf-ansi-can-60-descricao-geral-da-certificacao-para-produtos-quimicos-utilizados-em-tratamento-de-agua-potavel/>

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 countries: 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 previous quarterly report, the Moroccan Ministry of Health (MoH) requested a formal partnership for NSF's Strategic Alliance 2 project implementation in Morocco as it was identified to be a good tie-in to the Morocco National Water Committee's initiatives and efforts. With this partnership in place, in-person training on NSF/ANSI Standard 60 and NSF/ANSI Standard 61 was delivered in collaboration with the MoH and their office in Rabat, Morocco.

To best assure attendance by key stakeholders, NSF International provided financial support for the overnight lodging of ten (10) invited participants who do not live near the training venue. In addition to providing the venue, the Morocco MoH provided stakeholder outreach and invitation, in particular to members of the Moroccan National Water Committee who have been supportive of the Standards Alliance project. This promotion has included communicating the importance of developing a local standard addressing the health effects of products, materials, and chemicals used in the water sector.

It is noteworthy, that all stakeholders/members of the National Water Committee participated in the

training. Participation from these National Water Committee members offered opportunity to have clear input from all of them how they envision the best way of moving forward toward adopting or referencing the NSF/ANSI/CAN Standards.

Following the two (2) day training event in Morocco, there was a questionnaire and debrief meeting with the MoH and NSF where it was agreed to allow some time for the National Committee to discuss the best approach going forward for referencing and /or adopting NSF standards locally. The MoH indicated that the path forward should be clear by the end of the year. As such, NSF agreed to have a follow up meeting early January, 2023 during which NSF will elaborate on its technical advisory services and other ways to support Morocco community water initiatives.

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

In-person training on NSF/ANSI Standard 61 and NSF/ANSI Standard 60 was delivered October 19 and 20 respectively at Morocco’s Ministry of Health office in Rabat, Morocco. The presentation in French included an introduction of the presenters, USAID, ANSI, Standards Alliance: Phase 2, and NSF International followed by the standards development process and its value.

As was proposed by the Morocco MoH , the trainings were held with all stakeholder organizations concurrently (not individually by organization) over a two (2) day period at their office location. In addition to providing the venue, the Morocco MoH provided stakeholder outreach and invitations, especially to the members of the Moroccan National Water Committee, who have been supportive of the Standards Alliance project. Their promotion has included communicating the importance of developing a local standard addressing the health effects of products, materials, and chemicals used in the water sector.

One particular achievement is that all stakeholders/members of the National Water Committee participated, which offered opportunity to have clear input from all of them how they envision the best way of moving forward toward adopting NSF 61, including the use of a questionnaire. All stakeholders from the National Water Committee also participated to the training around NSF 60 standard, to continue to work towards its adoption. Unfortunately, there was no response from the private sector to the invitation to both trainings and, as a result, no attendance from private stakeholders. The team is considering leveraging its local consultants with more time to engage the private sector going forward.

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 of this activity continues to face delays because Ethical Apparel has had many challenges 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%.

Although activities could not be carried out under this reporting period, as the masks had not passed the test yet, they finally got approved in early 2023. 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.

ANSI will now consider its level of involvement in this next phase as approval for the masks has been very challenging and it has achieved its main objective which was to facilitate the masks production in Ghana which can now happen.

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. 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.

Particular focus was placed this quarter on partnering with the U.S. Trade Representative (USTR) on GRP and TBTs. To illustrate the team's success around implementing GRP around the partner countries of this activity, the work in Colombia was highlighted; where the team successfully institutionalized GRPs and overviewed efforts to formalize GRP implementation with the National Regulatory Authorities (NRAs) through checklists of international obligations. Based on the success the activity is having in Colombia, the team is now working with USTR to leverage the Coalition and MDRC websites to house a new series of GRP trainings by USTR. These trainings might be as simple as pre-taped recordings on GRP.

Relating to TBT, where the Coalition's focus remains centered around the identification of trade bottlenecks and resolve them; the team and USTR discussed a number of those bottlenecks, including

NOM 241 in Mexico, which was formalized into a Specific Trade Concern (STC). The objective at the end of this reporting period relating to partnering with USTR is to develop a WTO paper on the responsibilities of health authorities to implement trade obligations. USTR suggested there might be an opportunity for the next WTO Triennial Review (begins October 2023) to have a dedicated medtech component.

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. Offering training and increasing the capacity for women experts on the field was once again a priority for the team during this quarter. Successfully, the buy-in from female participants was extremely strong, amounting to close to 75 percent of all participants. The team is confident that by training women in the medical device sector it can offer more opportunities for them to participate more in the development of the economy in a sector that is also key for the safety and health of their population.

Africa

With the Africa Leadership Summit taking place under this reporting period USTDA considered efforts to launch an Africa-focused healthcare initiative in December on the sidelines of the Africa Leaders Summit. This initiative provides a framework for engaging and regularly convening with key private sector actors to advance a holistic healthcare agenda on the continent. The team is now listed as a formal partner for this initiative which will allow better interagency cooperation around medical devices standardization in Africa.

On 6-7 December, MDRC participated virtually in the African Medical Device Forum (AMDF) Technical Committee (TC) meeting. MDRC reviewed its envisioned 2023 trainings and formally proposed partnership on those trainings with AMDF. These trainings were proposed in alignment with the AMDF Chair, Strategic Plan, and 2023 Workplan.

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.)

The team led local project efforts in Q4 2022. An overview of the major developments is listed below:

Ghana

Pursuant to the work started in Q3 2022, the team continued to discuss with the with Ghana's Ministry of Trade and Investment (MOTI) and Food and Drug Administration (FDA) around the formalization of the MoUs for cooperation in this field and the formalization of the workstream. At the end of this reporting period Ghana indicated the Tier One MoU was with the Chief Director and awaiting input from the Ghana Standards Authority (GSA) before signature.

Kenya

The team engaged with the Medical Technology Industry Association of Kenya (MEDAK) during the Q4 of 2022 after having previously engaged and signing an MoU with PBB. Via this engagement the team is

working to advance the use of international standards in its country-specific workstreams and more broadly on the continent through the African Medical Device Forum (AMDF) and related organizations. As it relates to Kenya the focus of work centers around assessment's non-alignment with the MedTech sector, including improper differentiation between medicines and MedTech; and the Kenya Bureau of Standards (KEBS) Pre-Export-Verification of Conformity (PVoC) Program and its requirements for medical device market access in the country.

Moreover, the team held follow up meetings with PPB to develop options for executing capacity building programming. The team continues to work on the organization of in-person workshops to take place in 2023. Part of the development of the agenda for early 2023 is to work around PPB's interests in the MDRC-crafted regulatory procedure checklist to implement international reference documents and obligations. This checklist would help PPB and other Kenyan government authorities avoid any repetitive regulatory activities. As the MoU with PPB relevant language to PQM+ the team will coordinate upcoming trainings to ensure proper alignment.

Given that PQM+ secured additional USAID funding to support in-country COVID-19 vaccines development and related elements – with a particular focus on working towards WHO GBT Maturity level 3 cooperation in implementing both programs will be key to ensure that there is no duplication of efforts nor contradictory messaging to the partner country. In that sense the team has also during this reporting increased its cooperation with USAID's local mission in Kenya. It overviewed its structure, methodology, and engagement to-date with Kenya – including recent trainings in October and continued partnership with PPB. MDRC informed USAID Kenya that members of the project team intend to travel to Nairobi for MDRC-related meetings. The team noted that the US FDA and other stakeholders agree that the GBT+ assessment is not yet appropriate for medtech and is inconsistent with other WHO guidance documents, such as those pertaining to good regulatory practices. As such, this assessment has created additional regulatory bottlenecks for medtech in Kenya. MDRC and PPB's MOU includes specific workstream elements geared towards Kenya achieving Maturity Level 3. Because the local mission is working on Maturity Level 3 goals for Kenya and the fact the team has the only USAID project with the direct support of and alignment with the US FDA division responsible for medical devices there should strong alignment between the MDRC work and the one the local mission is carrying allowing for a strong cooperation in the country to advance this objective.

South Africa

The team in cooperation with the South Africa Health Products Regulatory Authority (SAHPRA) continued its work to finalize language for a joint Terms of Reference based on the work held during the workshop on GRP implementation in the medtech sector, held during Q3 of 2022. These sessions were intended to promote the utilization of GRP and use of international standards through trainings on GRP. The first session convened 19 representatives from NRAs and 119 from the private sector. The second session convened 16 representatives from NRAs and 124 from the private sector.

The next step is the organization of the anticipated schedule of trainings in Africa in Q1-2 2023, including a Tier Two virtual training in late January 2023. MDRC shared information on the MDRC-crafted GRP Checklist. While this tool was originally developed for government use in Latin America, the project has ensured the checklist's applicability and adaptability to other project countries. As this checklist creates a policy instrument to ensure the implementation of international reference documents and legal requirements, SAHPRA indicated interest in learning more about the checklist.

At the end of this reporting period the team has now finalized with SAHPRA the ToR with a scope not only limited to implementing lessons learned from COVID-19, but also establishing a resilient health regulatory system moving forward; since the team has unique expertise in medical devices relative to other projects, including extensive partnership with U.S. FDA/CDRH. The ToR is currently being signed by all parties.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

During this reporting period the team focused on increasing the coordination with the Association of Southeast Asian Nations (ASEAN) Consultative Committee for Standards and Quality (ACCSQ) and ASEAN Medical Device Committee (AMDC) to better ensure alignment between the Standards Alliance activity in Indonesia and the regional efforts towards standard harmonization around medical devices.

By bringing in ASEAN the team seeks to feature expert, technical training on the WTO TBT Agreement and legal obligations as it relates to GRPs and national commitments, as well as having sessions related to medical device-specific regulatory topics, in line with the priorities of the ACCSQ and the AMDC in training events set to take place in Q1 of 2023.

As it pertains to progress directly with the Indonesian government, the team organized a hybrid, small-group discussion with the Indonesian Ministry of Health officials. The training covered foundational GRPs, introduced Quality Management Systems (QMS), and facilitated a two-hour discussion. The discussion covered real-world case studies, benchmarking, reliance models, and MDRC's GRP checklist. The training convened 27 participants, 5 of which were from the private sector; it yielded positive feedback from all the different stakeholders and the team is now discussing next steps with the USAID Indonesian Mission.

Latin America

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

The Coalition led regional and local project efforts throughout Q4 2022. An overview of the major developments is listed below:

- Led the execution hybrid in-person programming in Boston to advance regional Tier Two GRP implementation. This included a hybrid Workshop on Self-Testing and a hybrid workshop for project country government representatives. Details of the series of trainings in Boston can be found in Section 3.
- MDRC provided capacity building resources through the Coalition website <https://www.interamericancoalition-medtech.org/regulatory-convergence/>.
- Mexico: 8 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. MDRC continued efforts to develop and approve checklists for implementing GRP in key governmental bodies. MDRC advanced several workstreams, including through the execution of a workshop on Conformity Assessment for Medical Devices and (SaMD).

- Peru: 6 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.
- Colombia: 50 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. See Activity 12.24 for more info.
- Brazil: 4 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.

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

Brazil

To continue pushing for better standards harmonization around medical devices in the country, the team participated in working group meetings for the nationalization of the ISO 15197:2013 - *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*; of which the IVD Office of ANVISA is participating in the work. The team is thus able to assist with its expertise when required, and also coordinate with the Brazilian National Standards Organization (ABNT) CB-36 working group on the Internalization of ISO 15197:2003.

Colombia

In Q4 2022, MDRC continued to lead the formal implementation and institutionalization of GRP in Colombia at both Tiers One and Two. 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. MDRC's focus will shift into formal training on those GRP requirements in Q1 2023. In Q4 2022, MDRC also continued efforts to implement GRP in other workstreams.

Of particular relevance to demonstrate the impact of the work the team has been conducting in Colombia is the finalization during this quarter of the PPE Guide created in partnership with the U.S. National Institute of Standards and Technology (NIST), the Colombian Institute of Technical Standards and Certification (ICONTEC).

Moreover, as part of the National Planning Department's (DNP) National Contest on Good Regulatory Practices (GRP), the Ministry of Health (MOH) was recognized for its recent formal approval and publication of GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. These requirements were implemented in the form of a regulatory tool updating the Ministry's processes and procedures. Recognized by the Contest under the "Institutional Adoption of Good Regulatory Practices" category, the tool was developed under the leadership of MDRC following 9 months of extensive coordination across the Government of Colombia. Those participating government stakeholders included MOH, DNP, Ministry of Commerce, and Public Function Department.

At the end of the quarter the team and the Colombia National Food and Drug Surveillance Institute (INVIMA) had also made significant progress related to the work for the *Ex-Ante and Ex-Post Evaluations*:

- *Ex-Ante Evaluation for Clinical Research*: MDRC estimated the ex-ante evaluation process was about 29% complete.
- *Ex-Post Evaluations of Decrees 4725 and 3770*: MDRC estimated that the ex-post evaluation process is about 69% complete.
- *Ex-Ante Evaluations of Decrees 4725 and 3770*: MDRC estimated the ex-ante evaluation process was about 7% complete.
- *Ex-Ante Evaluation for Good Manufacturing Processes (GMP)*: MDRC estimated the ex-ante evaluation process was about 39% complete.
- *Ex-Ante Evaluation for Emergency Use Authorization (EUA)*: MDRC estimated the ex-ante evaluation process was about 28% complete.

Mexico

In Q4 2022, the team continued efforts to develop and approve checklists for implementing GRP in key governmental bodies. These checklists will help build national quality infrastructure and facilitate compliance with international trade obligations. In turn, this will promote patient access to vital medtech and generate resilience for future health crises. MDRC continued to advance several workstreams, including addressing trade concerns presented by NOM 241.

To that end the team coordinated with key government stakeholders such as the new Director of International Affairs of The Federal Commission for Protection against Health Risks (COFEPRIS), to help push dissemination of the checklist. It also engaged with the National Directorate of Standards in Mexico, including the newly appointed General Director to start work around a proposal pertaining to implementing regulation of the Quality Infrastructure Law in the country.

Finally, the team presented on GRPs and Conformity Assessment at the 7th International Meeting of Mexico's Regulatory Professionals Association. This advances MDRC's objectives to promote GRP and regulatory convergence in the project country.

Peru

During this quarter the team continued its engagement with the Peruvian government to define the best partners inside the government to facilitate GRP and standards harmonization around medical devices in the country.

2.4 Implementation Challenges

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

Communication with ARSO can be complicated at times, as they are running multiple webinars throughout the month, and typically contact members within a very brief timeframe prior to webinars. The team has adjusted accordingly, and prepare as many materials in advance as possible, and then attempts to

accommodate ARSO's schedule. The last webinar was supposed to happen in December, but due to scheduling challenges, was again postponed and will be targeted to happen in January 2023.

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

CWSC noted that there were fewer responses to requests for interviews than anticipated due to the festive season, where many professional in the target countries take extended period of leave. CWSC expects to have better response in Q1 2023.

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 proved problematic for the U.S. Study Tour. It is hoped that there will now be sufficient time to process the Visas prior to the Denver meetings in June 2023.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

The biggest challenges are:

- Very time-consuming researching organizations, universities, and government ministries for contacts /stakeholders.
- Language barriers.
- Constraints on travel and in-person meetings caused by the Pandemic.
- Trying to overcome historical, colonial bias to the use of European-based codes and standards.
- .
- Programmatic barriers to quick adjustments and flexibility in altering strategies and methods for future market development.

Activity #7 – Increase the Flow of WASH Services

In order to aid in the effective implementation of SNI 122:2022, IAPMO recognizes the ongoing need to continue educating manufacturers about the importance of compliance with this new standard to ensure the safety and performance of their products as well as to make their products more competitive at the global market.

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

Government Mobilization

Ghana

In Q4 2022, MDRC experienced continued delays in engagement with those 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.

While MDRC welcomes the conclusion of those MOUs in Q1-Q2 2023, MDRC 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.

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.

Project partners, such as the FDA/CDRH, agree with and regularly express these concerns directly to the WHO.

As MDRC continues its work, those practices may hinder MDRC's ability to fully realize its project objectives. As MDRC outlined in-depth three examples of those practices in the Q2 2022 Report, they are briefly enumerated below:

- 1) Inappropriate Provisions of the WHO Global Benchmarking Tool Plus (GBT+)
- 2) The WHO does not follow its own guidance on Good Regulatory Practices in the development and publishing of WTO guidance documents.

3) Lack of adherence to the WHO Global Model Regulatory Framework (GMRF) stepwise approach. MDRC has recommended that its U.S. Government partners (such as the Department of Health and Human Services, Food and Drug Administration, and USAID) consider establishing a dialogue with the WHO to address these points in bilateral or multilateral fora. The MDRC has also recommended the GMTA consider a parallel dialogue with the WHO with a view to aligning international aid and capacity building approaches with NRAs.

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 will be critical to future successful capacity building. These efforts should extend beyond USAID projects and to all relevant capacity building projects. In South Africa, for example, MDRC has coordinated with USTDA and USAID to structure MDRC programming to be supportive of and complementary to USTDA's new project to provide capacity building to SAHPRA.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
1	N/A	ARSO	ARSO Webinars on Bioethanol	November 2022	70 participants
5	5.7	West Africa	Workshop on harmonization of petroleum standards	December 2022	50 participants
5	5.7	West Africa	ARSO Webinar on harmonization of petroleum standards	October 25, 2022	150 participants
8	8.3	India	Utility Management Standards Training Workshop #3	October 18, 2022	15 participants (4 F/ 11 M)
8	8.3	India	Utility Management Standards Training Workshop #4 Final	December 5-6, 2022	17 participants (6 F/ 11 M)
9	9.3	Brazil	NSF/ANSI/CAN Standards 60 training	October 25, 2022	52 participants
9	9.3	Morocco	NSF/ANSI/CAN Standards 60 and 61 trainings	October 19, 2022	2344 participants
12	12.10	Indonesia	Workshop: Small Group Discussion on GRP and QMS	December 7, 2022	27 attendees 17 female, 10 male (5 private sector)
12	12.11	LatAm	Workshop for LatAm Project Country Government Representatives	October 26, 2022	13 attendees 7 female, 6 male (0 private sector, all were regulators)
12	12.11	LatAm	Coalition Workshop on Self-Testing	October 23, 2022	42 attendees 20 female, 22 male (39 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 9 trainings to report which equals 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 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 November 2022.

For the upcoming quarter the team has set a target of 1.

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

As mentioned in the progress narrative section during this quarter no webinar took place as scheduling for the last event of the web series faced logistical delays. Therefore, the team did not reach its objective of 1 workshop this quarter.

In that sense the target for next quarter will be 1.

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

As stated during the narrative progress section of this report, during this quarter the team continue to focus on identifying the key stakeholders for the successful implementation of this activity. It has now developed a key list for all partner countries of contact points in water and sanitation and expects to be able to carry out trainings once the country needs assessment for those stakeholders is done.

Ensuring that the team has a clear picture of the needs and contact points that buy into the capacity building project will ensure that harmonization of standards in this sector can happen more smoothly, thus helping increase the health and safety of the local population and bolstering their participation into global trade and development.

In that sense, similarly to the previous quarters the target of 0 was reached.

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

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

The target for this activity was to hold 1 trainings event during this reporting quarter. Despite the fact that the visit from experts to the Orlando ASTM annual conference was not possible due to visa issues, this target was still met and even exceeded since a webinar option was put in place to allow key stakeholders to receive trainings on D02 on Petroleum Products, Liquid Fuels, and Lubricants, and a workshop in partnership with ARSO was also organized in October 2022.

After a meeting with the Senegal SDO Plans were set in place for an upcoming Workshop in Senegal in March 2023 and a U.S. Study Tour to take place in June 2023, the target for the upcoming quarter would then be 1.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

During this reporting period the target was 0 as the team focused on the defining partners for a renewed continental approach to the outreach effort for the adoption of the ACI building code.

As the defining of the strategy to develop this new phase of the activity is still going to spill out into Q1 2023 the target for the upcoming reporting period as it relates to organizing a workshop will also be 0.

Activity #7 – Increase the Flow of WASH Services

There were no expected workshops for Q4 and therefore IAPMO achieved its target of 0 workshops for this reporting period.

IAMPO is not expecting workshops in Q1 2023 and therefore the target is 0.

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

In Q4 2022, AWWA set a target of 0 for Africa and 2 for India. These targets were reached.

For the upcoming quarter, AWWA sets a target of 0 for India and 2 for Africa.

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

For Q4 2022, MDRC set a target of 2 workshops under this indicator, which it reached.

For Q1 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 480, which is lower than the targeted participants set at 599. This is explained by the fact that not all subawards were able to carry out all their workshops during this reporting period due to logistical delays. 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 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 reached as the Webinars with ARSO averaged 70 attendees per event.

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 8 for this quarter. Given that the team was able to host a webinar in December 2022 and also have a training in partnership with ARSO this number was well exceeded and reached 200 high level experts in the different trainings sessions offered by the team on the Harmonization of Petroleum Standards.

As the next workshop will take place in Senegal in partnership with ASN. The team thus sets the target for Q1 2023 at 20.

Activity #7 – Increase the Flow of WASH Services

There were no expected workshops for Q4 and therefore IAPMO achieved its target of 0 participants for this quarter.

IAMPO is not expecting workshops in Q1 2023 and therefore the target participants would also be 0.

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

In Q4 2022, AWWA set a target of 0 for Africa and 16 for India (10 for the first event on October 18, and 6 for the second event on Dec 5-6). These targets were surpassed for India with 32 participants joining the workshops.

For the upcoming quarter, AWWA sets a target of 0 for India and 28 for Africa.

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

² *Idem*

Under this reporting period for this performance indicator for Brazil, there is a total of one (1) workshops/trainings with **52** attendees. This target was reached as NSF had set a target of one (1) with **35** participants for Q4 2022.

Under this reporting period for this performance indicator for Morocco, there is a total of one (1), two (2) day workshops/trainings with **44** participants it has also reached its target for this partner country.

Given workshops were implemented in this reporting quarter, NSF sets for the first quarter of 2023 a target of **0** events in both countries, as the next quarter will focus on implementing the lessons from the trainings that were just rolled out.

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

For Q4 2022, MDRC set a target of **500** participants under this indicator. However, given that the team was only able to organize smaller in person workshops it only convened **82** participants. As defined by the team's reporting under the last quarter report MDRC had scheduled a Tier One Regional Forum for African stakeholders for Q4 2022. However, the event had to be postponed to Q1 2023. Given that the event has a virtual component it allows for the activity to invite more participants which explains the higher number for the target. The training, which will now take place under the next reporting period is essential to building good regulatory capacities and addressing barriers to trade by:

- Delivering high-level presentations on GRP policy implementation at both Tiers One and Two;
- Emphasizing the role of GRP in both recovery from COVID-19 and reducing barriers to trade;
- Participating in in-depth examinations of workstreams to implement GRPs, including timelines and plans for future implementation;
- Exploring efforts to document GRP implementation within pilot project regulatory agencies; and
- Facilitating long-term GRP collaboration among the project countries.

For Q1 2023, MDRC sets a target of **50** participants under this indicator.

5. LESSONS LEARNED

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

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. As well as including a topic on the existing funding opportunities at the level of US agencies; this was requested by the participants.

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

The three virtual workshops for India have been insightful for learning to provide the training in a virtual workshop. AWWA learned the need for additional opportunities for feedback and interaction to be included at more frequent intervals, and this will be included in the virtual workshops for Africa as a result. AWWA also learned at the in-person workshop in India that face-to-face interaction provides for more

back and forth and that India water professionals are more willing to speak up and in person.

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

For Brazil, the NSF/ANSI/CAN Standard 60 topic was expected by NSF to be of lower interest than the NSF/ANSI/CAN Standard 61 topic, presented earlier in the project timeline. While this was confirmed by a lower overall attendance to the NSF/ANSI/CAN Standard 60 webinar compared to the NSF/ANSI/CAN Standard 61, there were a larger number of registrants and attendees than expected, pointing to a stronger interest in NSF/ANSI/CAN Standard 60 than original thought.

For Morocco, NSF learned the value the Moroccan MoH’s support and collaboration. The MoH’s outreach and proposed integration of NSF/ANSI/CAN Standards into the Morocco National Water Committee’s discussions certainly contributed to the strong participation as attendance from in-country stakeholders. Not only did the Moroccan MoH provide access to stakeholders, who early in the project were difficult to access, but the MoH collaboration has been instrumental in NSF securing planned continued conversations with these in-country stakeholders on NSF/ANSI Standards and Water Management Planning.

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 organize multilateral hybrid in-person trainings alongside the October MedTech Conference. For in-person attendees, MDRC continues to learn how to effectively navigate COVID-19 protocols in addition to international travel restrictions/regulations.

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
1	N/A	West Africa	N/A	Workshop on Clean Renewable Fuel	Q1 2023	Online	TBD
5	5.5	West Africa	N/A	Training on gasoline testing standards	February 2023	Virtual	TBD

5	5.5	West Africa	N/A	Workshop on petroleum harmonization	March 2023	Senegal	TBD
5	5.5	West Africa	N/A	Study Tour in the USA around Committee meetings of ASTM Committee D02 on Petroleum Products	June 2023	Denver	TBD
8	8.3	Africa	N/A	Utility Management Standards Training Workshop #2	January 10-11, 2023	Online	No
8	8.3	Africa	N/A	Utility Management Standards Training Workshop #3	April 25-26, 2023	Lusaka, Zambia	No
9	9.3	Morocco	N/A	Technical advisory services on NSF 60 and 61	2023	TBD	TBD
12	12.6	Africa	N/A	Africa Continental Workshop: Good Regulatory Practices and its implementation in the Medical Device Sector	January 30-31 2023	Virtual	Yes