Standards Alliance: Phase 2

Quarterly Report

Q2 April 1st to June 30th, 2022

Submission Date: August 1, 2022
Version 1: August 1, 2022

Agreement Number: 7200AA19CA00012
Activity Start Date and End Date: July 12, 2019 to July 11, 2024
AOR Name: Eleanor Thornton

Submitted by: Leslie McDermott
American National Standards Institute
1899 L Street NW, 11th Floor, Washington, DC 20036
Tel: 202-331-3626
Email: lmcdermott@ansi.org

Table of Contents

1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date And End Date:	July 12, 2019 – July 11, 2024
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, ACI, CWSC, IAPMO
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	Q2 2022 – April 1st to June 30th, 2022

1.1 Program Description/Introduction

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

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

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

members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The second quarter of 2022 entailed the continued implementation of activities under all approved subawards and participation to the ARSO General Assembly. The MDRC program in particular continued to make significant progress this quarter via several webinars, outreach with key stakeholders, critical meetings, and the finalization of the Tier One Gap Analysis report on Good Regulatory Practice, and the participation in the Summit of the Americas. ANSI also continued to monitor the COVID-19 pandemic throughout Q2 and will continue to adjust activity implementation accordingly, as restrictions appear to be easing 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

Under this activity Pivot has been developing workshops on renewable fuel with ECOWAS member countries; and based on outreach and feedback from the Center for Renewable Energy and Energy Efficiency (ECREEE) Togo and Gambia were the two countries that showed strong interest in hosting a workshop on this topic during Q1 of 2022. Follow-up is continuing with participants to determine the next action steps in each country.

Pivot once again underlined that those countries were chosen because:

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

Out of the effort to promote renewable fuel in West Africa; Pivot has also undertaken a working relationship with ARSO to also develop workshop hosted by that body on Bioethanol. The parties have agreed to develop a five-part webinar series, scheduled to occur as monthly sessions from May through September 2022. Therefore, two session have occurred under this reporting period and will be reflected in the appropriate section of this quarterly report. Finally, proposals have been submitted for several in-person workshops in 2023, including Mozambique, South Africa, and Senegal; and planning for a virtual workshop in Mali in September 2022 is underway.

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

Partner countries: Continent Wide
During this quarter Personal Care Product Council (PCPC) and ANSI carried out a webinar on May 9, 2022 on Good Manufacturing Practices for Cosmetics. For this webinar, experts from PCPC provided an overview of the importance of Good Manufacturing Practices for cosmetics in ensuring consistent quality. Speakers expanded upon the ISO standard for cosmetics GMP and provide top-level insight into aspects of practical implementation. The webinar received positive feedback; and in that sense PCPC and ANSI aim at carrying another session in the upcoming quarter.

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

Partner countries: Ghana, Uganda, Zambia

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

CWSC completed the deskwork for each of the three countries and identified an initial list of governmental and nongovernmental contacts for each of the three countries to which CWSC will reach

out to interview to help answer four research questions (also developed this quarter). For example, CWSC has identified contacts at water and environmental ministries and contacts from CSOs, IOs, and nonprofits such as UNICEF, World Vision, CARE, CRS, WaterAid, amongst others. In Ghana, a few specific examples of who CWSC expects to speak to include: the Managing Director of the Ghana Water Company, the CEO of the Community Water and Sanitation Agency, the Minister of the Ministry of Sanitation and Water Resources, the Executive Secretary of the Water Resources Commission, and a representative at the Ghana Standards Authority.

CWSC developed general and specific interview questions for Q3's stakeholder interviews. These questions will help to guide the interviews and ensure that CWSC maximizes their time and gets the information needed. CWSC also expects that their answers will trigger additional questions and possibly necessitate additional meetings. Further, the stakeholders that CWSC interview are also expected to be those who will attend and participate in the launch of the country reports. Before beginning interviews, CWSC will provide updates to each USAID Mission with the list of interviewees included.

Some examples of the interview questions include:

Q #1: Has national-level law created a commitment to increasing access to drinking water and sanitation?

–Are there any additional relevant laws other than the ones we have reviewed (insert list) that we should review? Are there any regulations which govern the provision of water services? Which?

–Are there any relevant policies? How are policies adopted and can they be enforced? What is the process for public participation in law making, regulation making, and policy making? Is public participation required (by law)?

–Are the laws and regulations being implemented and enforced?

–How do you know the laws are being implemented and enforced? What types of indicators/criteria/factors do you examine to determine that the law is being implemented and enforced?

–How do you determine that the law is having the intended and desired impact?

Q #2: How does national-level law support the adoption and application of WASH standards?

–What is the process for developing and adopting WASH-related standards?

–What is the process for revising WASH-related standards?

–Are these processes set forth in regulation or policy? Can you provide the document? Who wrote the regulation or policy?

–Are these processes ever reviewed and changed?

–Where international standards exist and no domestic standard exists, are international standards adopted, or are unique domestic standards developed? How is that decision made? When there is a domestic standard, and an international standard is adopted later in time, is the domestic standard reviewed and amended (if necessary)?

–Which standards are compulsory? Which are voluntary? How do you decide which standards are compulsory or voluntary? Are there any standards which were originally voluntary which are now compulsory?

Q #3: How do national-level laws create an enabling environment for NQI related to WASH products, reduce barriers to trade in WASH products, and support efforts to increase access to safely managed water and sanitation?

–Are there any unique rules or requirements for foreign companies exporting WASH products to the country (Ghana, Uganda, Zambia) that are different from domestic companies that create

WASH products?
–Do foreign companies lose IP protections when they export their product to the country?
–Are the procurement requirements or procedures different for foreign versus domestic WASH products (e.g., more or less stringent)?
–Are public-private partnerships allowed, generally? Are there any differences in the governing rules or requirements when a partner is foreign v. domestic?
–Are there any examples of PPPs? What is their purpose? Have they been successful (at increasing access to WASH, improving the quality or variety of WASH products available to customers)?
–What kind of information is required to be made available to the public about WASH products/services? Is it different for domestic v. foreign companies?

Q #4: Examine workforce development generally in the WASH sector, including whether industry associations have been formed and whether a skilled workforce has been institutionalized through required certification processes.
–Have industry associations for WASH professionals been created?
–Are WASH professionals required to be certified? Which types of professionals or jobs require certification?
–What are the certification requirements (e.g. complete classes, receive a certificate, have a certain degree, attend classes during career)? How long does it take to be certified?

Activity #3.2 – Conduct in-person or virtual interviews with Ministries, regulators, National Standards Bodies, utilities, private sector partners and civil society organizations
Progress expected Q3 2022.

Activity #8 – Utility Management Standards Training for water sector utilities (Also appears in Indo-Pacific section)

Partner countries: Lesotho, Malawi, Zambia

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

A needs assessment survey was distributed to utilities and other related organizations in Zambia, Malawi, and Lesotho. Responses were received from 22 utility representatives, with those respondents as likely participants in the Africa workshop series.

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

Activity on schedule with one update. The order in which the different AWWA standards are addressed in the workshops will be slighted adjusted for the Africa workshops from that which took place for the India workshops, and additional interactivity will be included.

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

Based on the need assessment received from the countries the first virtual workshop is scheduled for September 7th and 8th for 3 hours each day.

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

At the beginning of April 2022, ASTM staff followed up with the Senegalese focal point to further consider setting up Proficiency Testing Programs (PTP) programs with about 15 labs throughout Africa who are members of the African Refiners and Distributors Association (ARDA). In addition, the contact was provided a free trial version of ASTM's Compass platform to try out the platform to access the most current standards for his refinery.

Although not directly related to the Standards Alliance phase 2 project, ASTM attended the ARSO GA in Cameroon at the end of June 2022 and was able to touch base with Director Generals of 3 out of 4 SA2 partner countries, for this activity, focal point national standards bodies. Ghana[1], Nigeria, and Senegal were all supportive of the program and endorsed its objectives.

Activity #5.7 – Host an exhibition booth and hold a two-day working group meeting in conjunction with the well-attended exhibition and conference, the Nigerian Oil and Gas Conference and Exhibition (NOG).

Much of Q2 was spent planning the execution of the second face-to-face engagement which took place in Lagos, Nigeria July 4-7, 2022. The original plan to hold the Nigeria meeting in conjunction with the Nigeria Oil and Gas Conference to be held in Abuja had to be changed to accommodate petroleum laboratory visits which were only available in Lagos.

The Workshop preparation for the July Nigeria event included planning for the following objectives:

- Highlight the benefits of harmonized standards and review of relevant ASTM standards and adaptation to national or regional standards
- Improve direct access to shaping the content of standards through participation in ASTM/API activities
- Introduce, share examples, and make suggestions, on how to implement and make use of the World Trade Organization Technical Barriers to Trade Agreement decisions and principles related to international standards, good regulatory practice and national quality infrastructure.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

[1] Of particular relevance was the meeting with Ghana's director general. See https://www.ghanaweb.com/GhanaHomePage/business/ASTM-pledges-support-for-Ghana-s-petroleum-industry-1571921

Partner countries: Kenya, Tanzania, Uganda

Activity #6.2 – MEETINGS (Virtual and In-Person): Begin meetings with interested parties from government ministries, standards organizations, engineering associations, and educational institutions to introduce ACI, establish relationships and raise awareness and understanding about the benefits of using ACI codes/standards and ACI code adoption. Includes an Africa wide webinar to introduce ACI to all interested parties in Africa, followed up with a survey to identify the countries with the highest development potential.

The ACI program stalled during Q2 of 2022, as organizations who were initially interested in cooperating with ACI, lost interest and stopped communicating. This loss of momentum has resulted in a re-evaluation and reformation of our strategy for Africa. The team is planning a half-day webinar for August 24, 2022, that will be open to all eligible USAID countries in Africa. Invitation for the webinar are expected to be sent at the end of July 2022.

ACI Code Adoption Engineer has developed a preliminary program for the virtual webinar, and started the internal ACI process with staff who are involved to prepare for said webinar.

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, Philippines (pending appropriate approval)

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

The public comment period on the draft faucet standard was completed on 8 May 2022. There were 17 comments received from public stakeholders – 15 editorial comments and 2 substantial comments. Substantial comments necessitated additional Technical Committee Meetings. The first meeting was held virtually on 10 June 2022 with six stakeholders from BSN and IAPMO to revise the draft standard to address the editorial comments that were received and to prepare responses to the substantial comments.

BSN hosted a hybrid meeting of the Technical Committee 77-02 on 15 June 2022 involving 45 stakeholders. The purpose of the meeting was to discuss and resolve the substantial comments that were received. The meeting concluded that for water meter faucets, the life cycle testing will be for 100,000 cycles only for this category. Subsequent to the meeting a final revised draft of the SNI was submitted to BSN for approval.

Two documents are attached as appendices to this report. Appendix 1 is the official BSN report on public comments received on the draft of SNI and the Technical Committee's resolution to those comments. Appendix 2 is the final draft of the SNI following the public comment period that has been prepared for adoption of BSN.

The final draft standard contains formal references to the following internationals standards developed by

U.S.-based organizations:

1. ASME A112.18.1/CSA B125.1 Plumbing supply fittings
2. ASTM B117, Standard Practice for Operating Salt Spray (Fog) Apparatus
3. ASTM B571, Standard Practice for Qualitative Adhesion Testing of Metallic Coatings
4. ASTM D3359, Standard Test Methods for Measuring Adhesion by Tape Test
5. ASTM D968, Standard Test Methods for Abrasion Resistance of Organic Coatings by Falling Abrasive.

IAPMO's faucet standard development process is set out as following:

No.	Activities	Output	STATUS
1	SNI Formulation for Water Faucets and Plastic Pipes		
1.0	Convene Technical Committee – Q3 2021	Cmte. Established	COMPLETE
1.1	Prepare draft SNI (RSNI) Standards – Q4 2021	RSNI 1	COMPLETE
1.2	Technical Committee Meetings - Q1 2022	RSNI 2	COMPLETE
1.3	Develop a Consensus Draft – Q3 2022	RSNI 3	COMPLETE
1.4	Release RSNI for public comments and inquiry – Q4 2022	Public Input	COMPLETE
1.5	Technical Committee meetings on RSNI 3 and public comments – Q4 2022	RSNI 4	COMPLETE
1.6	Technical Committee meetings on RSNI4 and public comments – Q1 2023	RSNI 5	N/A
1.7	Finalization of RSNI 5 – Q2 2023	RASNI	COMPLETE
1.8	Adoption by BSN – Q2 2023	SNI	ADOPTED 7/18/2022
	IAPMO LAB DEVELOPMENT		
2	Implementation of Mandatory SNI		
2.1	Preparation of Risk Impact Analysis (RIA) – Q3 2023	RIA	
2.2	Meeting on RIA with Ministry of Industry – Q3 2023		
2.3	Proposal on the implementation of mandatory SNI to Minister of	Proposal	

	Industry and BSN – Q4 2023		
2.4	Drafting of certification scheme – Q2 2024	SK Menteri Perindustrian	
2.5	WTO Notification – Q2 2024	Notice	
2.6	Establishment of SK Pemberlakuan and Penunjukkan LSPro and Lab – Q4 2024	SK Pemberlakuan	

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

No progress to report as the project cannot receive concurrence.

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

No progress to report as the project cannot receive concurrence.

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

No progress to report as the project cannot receive concurrence.

Activity #8 – Utility Management Standards Training for water sector utilities (Also appears in Africa section)

Partner countries: India

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

AWWA completed delivery of the first workshop in India which was held virtually on April 27-28th. The virtual workshop lasted approximately 3-1/2 hours on each of the two days, and was attended by participants from 16 utilities, and included over 35 participants from Indian water and wastewater utilities. All attendees were provided with pdf versions of the first two ANSI/AWWA Standards to be covered in the workshop series (ANSI/AWWA G400 – Utility Management System and G200 – Distribution Systems Operation and Management). Follow-up monthly check-in calls with the Indian participants were held on May 24 and June 22. Each of the check-in calls lasted approximately 1-1/2 hours and provided participants an opportunity to have their homework items checked and to have any questions answered.

LATIN AMERICA

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

Activity #9 – Community Water Systems – Standards for safety and risk management (Also appears in Middle East North Africa section)

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 the outreach to stakeholders was related to broad dissemination of invitation to the NSF/ANSI/CAN Standard 61 scheduled training event. Registration for the training was open and free of charge to all interested in attending. Awareness of the training, as an invitation, was sent to a list of stakeholders with whom NSF had identified and broadly advertised on NSF's media. ANSI also disseminated the notification of the training via their channels and shared it with USAID.

Activity #9.3 – Hold trainings to address barriers to trade and awareness of other issues.

The NSF/ANSI/CAN Standard 61 training presentation slides were shared with USAID and ANSI in both Portuguese and English for review, largely for use of logos and format. The training material covered introductions of the presenter, USAID, ANSI, Standards Alliance: Phase 2, and NSF International followed by the standards development process and value, and an NSF Standard 61 detailed technical overview. Following ANSI and USAID review of the slides, the training was pre-recorded in Portuguese. Using platform ON24 (https://www.on24.com/) the recording was played live on **June 28 2022**; **with a strong attendance of 100 attendees from 194 registrants**. As the implementation in Brazil enters the Application phase of the project, there will be engagement with interested stakeholders on how NSF can be useful to strengthen regulatory, technical and/or application of standards within the country. Additionally, starting on July 11, 2022 the recording of the workshop will also be available on the NSF website.

As mentioned in the Q1 report, NSF/ANSI/CAN Standard 60 and Standard 61 represent different product types, therefore these two standards will be held as two separate training events. During 2022 Q1, the NSF/ANSI/ CAN Standard 60 slides were prepared by NSF and reviewed by ANSI and USAID. Pre-recording, advertisement and execution of the NSF Standard 60 training event will be the focus of 2022 Q3/early Q4 for Brazil. NSF's Brazil trainer is coordinating with NSF Marketing to arrange for the pre-recording and to set a date for the virtual training event to be promoted and executed in the same manner as the NSF Standard 61 training event.

MIDDLE EAST NORTH AFRICA

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

Activity #7 – Increase the Flow of WASH Services (Also appears in Indo-Pacific section)

Partner country: Jordan, No progress to report as the project cannot receive concurrence.

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

Partner country: Morocco

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

The Needs Assessment phase was completed to inform the finalization of the training materials. Four general themes emerged from the Needs Assessment: (1) general understanding of standards, (2) community health impact, (3) NSF Standards, and (4) impact on cost/business drivers. The project in Morocco now will move to the Training phase and NSF will develop training materials to address these interest areas, recognizing that the different audiences (manufacturers versus regulators) and tailoring the material accordingly. The dates for training have not yet been projected.

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

NSF met in-person with the Moroccan Ministry of Health, ONEE (Office National de l'Energie et de l'Envioronnement), IMANOR (Institut Marocain de Normalisation) and Redal (Veolia), and Amitech Maroc. These key stakeholders provided the necessary input to gauge interest in NSF/ANSI/CAN Standards 60 and 61 and for NSF's training on these subjects.

It is relevant to underline that the representative from the Ministry of Health was at the origin of the decree on potable water, setting the legislation for its quality in the kingdom. This is based on 2 norms:

- NM 03.7.001 on the quality of the water aimed for human consumption, covering all waters for drinking, cooking and other domestic uses, in public and private premises whatever is the origin and whether they are distributed through a distribution network or via tank-trucks or tank-boats. It is also applicable to bottled spring waters but not bottled mineral waters, which have specific regulations.
- NM 03.7.002 on the Control and monitoring of water in public distribution networks. This norm has been specifically developed to create an analytical plan for the utilities (public and private) distributing water to the Moroccan population

There is another norm existing regarding Water Safety Plans (WSP) which isn't translated yet in the Moroccan water regulation but is planned to be implemented by potable water distributors to improve the reliability of their networks. The WSP relating norm should integrate the legislation in the course of 2023.

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

Material Development Update: With completion of the Needs Assessment occurring during this reporting period, there was ongoing refinement of the training materials. Training dates and venues are yet to be determined.

2.3 COVID-19 Related Activities Implementation Progress

AFRICA

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

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

Partner country: Ghana

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

The feedback and test results have required Ethical Apparel to resource the mask fabric options again and the next round of sampling is due in Ghana to make into surgical masks by end of August 2022; originally this was expected in April but lockdowns in China have furthered delayed the process. Therefore, the new stated objective is to start training activities in Ghana in October 2022. Despite delays with production of surgical masks, Ethical Apparel has been able to produce a large quantity of general use masks which they are currently selling with Ghana – currently they are able to produce one million general use masks per month.

GLOBAL

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

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

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

Global

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. Please see Section 3 for a breakdown of the engagement of women in all MDRC capacity building exercises.

Africa

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

Regional:

In Q2 2022, MDRC published the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One Working Document. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. The Tier One Working Document has been reviewed by USAID and aligns with USAID branding requirements. This Working Document remains a *live document*. As more input and feedback from governments and relevant stakeholders are received, this report may be updated throughout the project.[2]

[2] The Tier One Gap Analysis is a global document and as such information included in this report extends to all three regions of work for the activity #12 of the SA2 program.

Activity #12.5 – Tier One and Two Local Meetings/Trainings (Preliminary dates are included below and are subject to change.)

MDRC led local project efforts in Q2 2022. Details of each meeting and training may be found in Section 2.1 Progress Narrative and Section 3 Stakeholder Participation and Involvement. An overview of the major developments is listed below:

Ghana:

The team held a formal meeting with regional Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. At the end of Q2, MDRC's USG partners reported significant interest of Tier One government stakeholders in partnering with MDRC.

The continued the effort undertaken under Q1 with the Ghana's Ministry of Health. However, the Ministry has not been as responsive as anticipated and as such USAID agreed to share a more appropriate point of contact at the Ghana Health Service.

Under this quarter the team expanded its outreach to other ministries and touched base with the Ministry of Trade in June 2022. The Ministry of Trade noted its interest in the Tier One Working Document and desire to work on items related to adopting international best practices, improve the standards-setting process, and good regulatory rulemaking. The Ministry of Trade confirmed it would reach out to the Ministry of Health to coordinate joint engagement with MDRC.

Kenya:

There were no formal meetings with Kenya's government Tier One and Two stakeholders. However the team maintained regular correspondence and informal conversations with stakeholders such as PPB; which is undergoing the GBT+ assessment and has had very limited bandwidth to process the draft MOU developed in Q1 2022.

South Africa

The engagement in South Africa was strong in Q2 of 2022, with multiple formal meetings with Tier One and Two stakeholders.

introduced the project, its objectives, and work in South Africa to the SAMED Regulatory Committee. MDRC overviewed its workstream with the South African Health Products Regulatory Authority (SAHPRA), including its envisioned calendar of workshops. While the MDRC workstream focuses on procedural aspects of capacity building with SAHPRA, this complements SAMED's workstream with SAHPRA on technical elements. MDRC and SAMED emphasized that the implementation of these workstreams will be done in close coordination between SAMED and MDRC, with input from the Regulatory Committee. MDRC clarified that the content of the workstreams and their workshops are crafted jointly with SAHPRA, ensuring an aligned and collaborative approach. MDRC noted the future U.S. Trade and Development Agency (USTDA) workstream with SAHPRA and MDRC's desire to closely

coordinate capacity building with that initiative. By the end of April 2022 MDRC provided SAHPRA with draft Terms of Reference (TOR) that guide the implementation of the MDRC workstream with the agency. The TOR were shared with ANSI and USAID for their review and input. SAHPRA's legal team intends to review this document and revert back with any edits in early Q3 2022. delays to workshop execution associated with the TOR approval, the attendees decided to target the first couple weeks in August for the first workshop on GRP and their implementation in the medtech sector. MDRC agreed to begin contacting speakers to secure their availability for the workshop.

During this quarter the team also reached out to Department of Trade, Industry and Competition (DTIC) to involved them as a stakeholder under this project and is working of formalizing this relationship.

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:

Mecomed informed MDRC that its Medtech Forum in June has been postponed to the end of the year (November/December 2022). This aligns with MDRC objectives as the project would like to execute various local trainings prior to such a regional event. The attendees also continued discussions on the establishment a GMTA Africa Working Group.

The team also engaged with Mecomed's Sub-Saharan Task Force (SSA), The South African Medical Technology Industry Association (SAMED), and MedTech Europe to continue discussions on the creation of a GMTA Working Group (WG) for Africa. A proposal for the creation of the WG at the GMTA was outlined, and initial work items, stakeholders, and structure have been under discussion early in the quarter. In May of 2022, GMTA and Global Diagnostics Alliance (GDA) approved the creation of an Africa Working Group. This group's principal and initial scope of work will be regulatory convergence, including MDRC workstreams and objectives. This WG has had the grass-roots support of MDRC partners SAMED and MECOMED, who will help steer the WG's leadership. The WG constitutes an African coalition for regulatory convergence in the medical technology sector – a significant MDRC MEL Plan milestone.

In June 2022 the team and Mecomed discussed the timing of the next GMTA Africa WG meeting and its potential agenda. This may include an MDRC briefing on GMTA-WHO dynamics and its context in MDRC implementation; including the organization of a workshop in Kenya in October 2021.

Indo-Pacific

Activity #12.9 – Tier Two Local Meetings/Trainings

Indonesia:

Early in the quarter the Ministry of Health requested information on how other countries issue GMP certifications and structure their pre- and post-market medical device regulatory bodies. MDRC offered to compile a document overviewing relevant information on how medical device regulatory bodies are organized and issue GMP certification, including case studies. MDRC shared that document with the Ministry on 14 April.

The sharing of information with the ministry allowed for buy in to develop a webinar series to be carried out by the team with relevant local stakeholders during this reporting period:

On 15 June, MDRC hosted the first of the two-part webinar series on GRP and medical device regulation. This was the first local capacity building event held by MDRC in Indonesia. The webinar was executed in collaboration with the Indonesian Ministry of Health and University of Gadjah Mada. There was strong support from the Ministry of Health's senior officials, including the Director-General for Pharmaceutical Services and Medical Devices, who delivered the introductory remarks. Over 170 participants attended the webinar.

On 22 June, MDRC hosted the second of the two-part webinar series on GRP and medical device regulation. Around 112 participants tuned in at its peak. Materials from both webinars are available on the MDRC website. MDRC is also in discussions with the Ministry of Health on topics and agenda for additional training session(s).

Vietnam:
MDRC coordinated extensively with local Tier Two stakeholders to initiate a formal workstream in the project country under DMEC. This includes regular correspondence, informal conversations, and collaboration in resource development.

Activity #12.10 – Tier Two Regional Meetings/Trainings

MDRC collaborated with the ITA to coordinate the future execution of a Tier Two regional training. The workshop would be hosted alongside or in consultation with the ASEAN Consultative Committee on Standards and Quality (ACCSQ) and/or the ASEAN Medical Device Committee (AMDC) under the ACCSQ. MDRC worked to share a concept note identifying preliminary topics for the training with ITA.

Latin America

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

The Coalition led regional and local project efforts throughout Q2 2022. Details of each meeting and training may be found in Section 2.1 Progress Narrative and Section 3 Stakeholder Participation and Involvement. An overview of the major developments is listed below:

- Led the planning and execution of hybrid in-person programming in Los Angeles, CA to advance regional GRP implementation alongside the Summit of the Americas
- Led the execution of 4 trainings in the region, providing capacity building resources through the Coalition website https://www.interamericancoalition-medtech.org/regulatory-convergence/.

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

The Coalition supported the execution of the International Webinar Series event on "The Use of Self-Tests in the Fight Against COVID-19." The webinar was organized alongside the Latin American Alliance

for In Vitro Diagnostic Development (ALADDIV), the London School of Hygiene and Tropical Medicine, the International Diagnostics Centre, and FIND, the global alliance for diagnostics. With 80 attendees, the event convened representatives from 13 countries, 25 from government authorities and 55 from industry.

On 28 April, the team met with the Pan American Health Organization (PAHO) and continued discussions on the Technical Cooperation Agreement, for which PAHO is evaluating the Coalition's submitted documentation. PAHO informed the Coalition that it is continuing its efforts to translate IMDRF documents to Spanish. Half of the documents were translated and awaiting internal approval for publication. The Coalition provided background on its events in June, including on the importance for advancing the implementation of GRP. The Coalition spoke to its coordination with the Inter-American Development Bank (IDB) and the Americas Business Dialogue (ABD).

Activity #12.13 – Recognition of deliverables at the Summit of the Americas

Between 6-8 June, MDRC through the Inter-American Coalitions for Business Ethics and Regulatory Convergence in the Medical Technology sector held a series of events and trainings alongside the Summit of the Americas. Those events prominently featured MDRC deliverables, including efforts to advance GRP in all three regions. The events included:

- 6 June: Meeting of the Coalition for Regulatory Convergence
- 7 June: Joint meeting of the Inter-American Coalitions
- 8 June: MDRC workshop to advance GRP implementation

The events convened leaders from the private and public sectors, including those stakeholders responsible for implementing GRP in Brazil, Colombia, and Mexico.

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 over 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 continues 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

Activity #12.16 – Tier One and Two Implementation Meetings and Workshops with Project Countries and regional stakeholders (Q3 2021 – Q2 2022)

Brazil:

During this reporting the period the team engaged with representatives from the Ministry of Economy to discuss potential areas for collaboration. The Secretariat for the Advocacy for Competition and Competitiveness (SEAE) proposed working on improvements to the Regulatory Cost Calculator, a tool

that aims to increase transparency about regulatory costs in the country. MDRC expressed interest and requested information on the budget needs required to implement those improvements. SEAE was interested in meeting with other authorities to exchange experiences and best practices for implementing GRP. MDRC and SEAE will continue discussions on these proposals.

Colombia:

The MDRC team continues to have strong buy in with the Colombian government to pursue the implementation of the program's objective during this quarter. However, while all workstream elements have advanced, the evaluations for Clinical Research, EUA and GMP will be behind schedule. This is a result of the fact that the Ministry of Health doesn't employ a person with the required economic profile to conduct some elements of the evaluations.

The cooperation with the Colombian government during this quarter continued around of the ex-post evaluation for decrees 4725 and 3770 with the Ministry of Health, the National Food and Drug Surveillance Institute (INVIMA), National Planning Department (DNP) via several key meetings. Of particular relevance is the fact that the team and the Ministry of Health aligned on the necessary steps to initiate public consultation, or "citizen participation," on the problem trees for under Decrees 4725, 3370, and Clinical Research. This is the first opportunity in which stakeholders can participate in the evaluations. At the end of the quarter the team met with the Planning office of INVIMA regarding the ex-post evaluation of the Decrees 4725 and 3770, to identify which procedures are associated with the products that are being evaluated so that they can be included in the evaluation going forward.

On the ex-ante evaluation on clinical research, the team pursued its engagement with the Ministry of Health and INVIMA to continue the identification of stakeholders for the GMP evaluation. As of this closing reporting, MDRC estimates that the ex-ante evaluation process was about 22% complete (was 11% under Q1 2022).

Moreover, during this quarter, the MDRC team also met with DNP to confirm that DNP's updated processes and procedures are ready for review to ensure alignment with the existing regulatory improvement policy and the Ministry of Health. Once formally adopted, training and application on the new processes and procedures will begin. MDRC estimated this entire process was about 65% complete at the end of this reporting phase, as opposed to 50% under Q1 2022.

The National Institute of Standards and Technology (NIST) has developed a set of guides on product compliance requirements in specific industry sectors. The guides include information on Federal and State regulatory frameworks, voluntary standards frameworks, applicable voluntary standards, mandatory technical regulations, and conformity assessment procedures for each sector. Colombia requested the development of a PPE Guide, and the U.S.-Colombia PPE Working Group (WG) was formed. The PPE Working Group consists of representatives from NIST as the U.S. lead, as well as ANSI and the MDRC staff to support the ongoing discussions, and the Colombian representatives include technical staff from the Colombian Institute of Technical Standards and Certification (ICONTEC) in close coordination with the Colombian Ministry of Commerce, Industry and Tourism (MinCiT). The WG convened three separate times this quarter to continue to develop the separate U.S. and Colombian PPE Guide drafts documents. The PPE Working Group plans to share draft versions of their respective PPE Guides in the beginning of July and anticipates to have final versions available before the end of August pending any necessary translation.

Mexico:

The continued the implementation on several fronts:

- It informed COFEPRIS that it is nearing completion of the position paper on NOM-241. COFEPRIS formed a working group to update NOM-241, to which MDRC shared the position paper on May 9, 2022.[3] COFEPRIS shared that it is still working to set up a meeting with its IT department regarding the creation of an online system to track project performance. This tracker is being called "TrackerPris.". On 26 May,2022, the Coalition collaborated with the COFEPRIS and Health Canada to organize a Workshop on ISO 13485 Certification. The workshop overviewed the perspectives of a National Regulatory Authority (Health Canada), a Standards Developing Organization (AMII) and an Auditing Organization (DEKRA) on the Certification Process on ISO 13485. The workshop convened 13 countries, 191 NRA representatives and 205 industry representatives.
- Carried out discussions on NOM-240, a regulation that pertains to Good Manufacturing Practices (GMP).

Peru:

During this quarter the team engaged with the Undersecretary of Regulatory Simplification and Analysis of the Public Management Secretariat, to confirm the support by the Office of Regulatory Quality Analysis ("Análisis de Calidad Regulatoria," ACR) for the efforts led by MDRC in the triennial review of administrative procedures of DIGEMID for Medical Devices. At the end of the quarter the ACR and Medical Device Joint Committee, started to share strategies for technical discussion with the Directorate General of Drug Supplies and Drugs (DIGEMID).

2.4 Implementation Challenges

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

Communication with ARSO can be complicated as they are running multiple webinars throughout the month, and typically contact members within a very brief timeframe prior to webinars. Pivot attempts to mitigate the issue by preparing as many materials in advance as possible, and then adapt to the schedule that ARSO can work with.

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

[3] This paper includes feedback from AdvaMed, AMID, and the Mexican National Chamber of the Pharmaceutical Industry (CANIFARMA), and will be share in English and Spanish

CWSC identified that it is very difficult to identify the people working on issues related to the intersection of NQI, WASH, and legality. CWSC experienced this throughout the years of doing this work, but in preparing for fieldwork they are always reminded of how difficult it is to identify the people/organizations doing the work and their contact information. Governmental stakeholders often does not have official email addresses. However, CWSC will leverage existing contacts to identify any missing contacts or contact information.

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

Originally the Workshop on in Nigeria was supposed to take place in Abuja, but was moved to Lagos which ended causing significant delays in its preparation.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

The biggest challenges are all related to the organization of webinars or hybrid workshops. The process remains very time-consuming with researching organizations, universities and government ministries for contacts /stakeholders; the language barriers is also an issue. Finally, the constraints on travel and in-person meetings caused by the pandemic are still a factor and impact the ability to organize workshops in certain locations.

Trying to overcome historical, colonial bias to the use of European-based codes and standards remains an overarching issue working in the region.

Activity #7 – Increase the Flow of WASH Services

One of the substantial comments IAPMO received from a local manufacturer related to life cycle testing required. Based on additional testing data that was submitted, a resolution was reached between the manufacturer and the technical committee to reduce the life cycle testing requirements to 100,000 cycles.

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

AWWA notes that the time difference of 11.5 hours between Denver and India does pose some scheduling challenges for virtual workshop delivery in India. The early morning in Denver and late afternoon/early evening in India time was chosen to provide the best compromise and has worked fairly well. AWWA will continue to monitor any effect on participation from the Indian utilities. Additionally, delivering the information on a virtual platform does limit participant interaction and immediate feedback, requiring extra efforts to ensure understanding of the material.

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

Morocco:

IMANOR raised the concern that a specific standard for the country could limit the number of potential suppliers to fulfill the local market needs, leading to price increase as manufacturers would try to get added value for an additional certification. Fear was voiced that this would lead to a situation close to the one observed in France or Germany of only a limited number of certified suppliers, long waiting list to get product certified (up to 2 years) and prices artificially maintained at a high level. However, because currently there are not many of these products in the Moroccan market, besides plastics, produced,

manufactured or assembled locally, NSF believes that this situation should be able to be prevented.

As a result of learning that some countries (including Morocco) included NSF/ANSI/CAN Standards 60 and 61 into their national legislation 'as is', since they are referring to US federal code, the NSF Regulatory Team plans to enquire in early Q3 the issue of "How a country can include a reference to another country's legislation in its own?". This question was raised by Moroccan government stakeholders and thus need to be addressed before training on those standards can fully begin.

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

Extreme delays in obtaining the certification for the surgical masks, which in turn prevent the beginning of the trainings with GSA which constitute the main implementation component of this activity.

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

Government Mobilization

One major implementation challenge in Q2 2022 was workstream execution delays related to slower engagement by some project country governments.

In Indonesia and Vietnam, MDRC experienced long periods between government stakeholder responses to project outreach. This was coupled with the observance of local religious holidays in January/February 2022, leading to a delay in the workstream development process. However, both countries' Tier Two government stakeholders remain extremely interested in partnering with the project. In Indonesia, MDRC obtained final approval by the Ministry of Health and executed two virtual capacity-building trainings for Indonesia in Q2 2022, with plans for additional topical trainings in Q3 2022. The process of workstream development continues in Vietnam with some delays, and is with the Acting Minister of Health for final approval.. However, if delays continue, MDRC will work with USAID and ANSI to reevaluate its allocation of resources to the project country.

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

MDRC has been working with local and regional stakeholders to continue outreach with Ghana's Tier One and Two agencies. This includes the U.S. Trade Representative, Department of Commerce, and Department of State. In Q2 2022, MDRC received word from the Department of Commerce that through its engagement with the Government of Ghana on MDRC that the Ministry of Trade might be interested in the project. MDRC is working with those stakeholders to identify potential new contacts at the Tier Two level to renew conversations with the Government of Ghana. In Project Year 3, with the potential creation of a Nairobi-based MDRC Liaison, MDRC will explore re-examining its level of engagement with Ghana to maximize effectiveness of capacity building resources.

In Kenya, PPB has been undergoing the Global Benchmarking Tool Plus (GBT+) assessment and has had very limited bandwidth to process the draft MOU submitted in Q1 2022. See below section on WHO Medtech Guidance for more information. MDRC has scheduled a tentative call with PPB for the first week in Q3 2022 to gain a deeper understanding of the state of play in the agency. This will help MDRC determine the feasibility and timeline of hiring an in-country liaison as well as overall project implementation in the country.

WHO MedTech Guidance

MDRC has included 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 in PY3, those practices may be hinder MDRC's ability to fully realize its project objectives. Three examples are outlined below:

1) **Inappropriate Provisions of the WHO Global Benchmarking Tool Plus (GBT+).** Through MDRC's engagement with Kenya's PPB, it has witnessed the efforts of a project country MD NRA to comply with the terms of the GBT+. In MDRC's opinion, GBT+ is not yet adequate or appropriate for use in assessing MD NRA medtech maturity level. This is in part because it has not sufficiently differentiated medtech from medicines in its provisions. MDRC also maintains that the premature roll-out of the GBT+ may result in MD NRAs incorrectly understanding that a positive WHO assessment is an approved measure of their medtech regulatory readiness when that may not by the case. This presents substantial risk to critically limiting patient medtech access and effective and timely COVID-19 response.

2) **The WHO does not follow its own guidance on Good Regulatory Practices in the development and publishing of WTO guidance documents.** In MDRC's work leveraging international guidance documents to build regulatory capacity, it has observed several concerning practices in the WHO's development and publishing of WTO guidance documents. Those include: not routinely providing advanced notice of comment periods on WHO documents; establishing arbitrarily short comment periods; not conducting meaningful review of comments; not routinely responding to comments or providing applicable rationale on their assessment of the documents. These practices are not in compliance with the WHO's own guidance on GRP or with broader multilateral GRP benchmarks such as those of the OECD or WTO. MDRC believes these practices limit the relevance and effective applicability of WHO documents on MD NRAs. They also present a risk of NRAs implementing WHO guidance for MDs with the understanding that such guidance is appropriate and conducive to health and COVID-19 response when that may not be the case.

3) **Lack of adherence to the WHO Global Model Regulatory Framework (GMRF) stepwise approach.** MDRC follows the WHO GMRF stepwise approach, encouraging NRAs to scale their regulatory activities to their capacities and to prioritize regulatory fundamentals. This approach is critical to appropriately building regulatory capacity in project countries. MDRC has observed WHO acting counter to this method in contradiction to MDRC efforts supporting WHO guidance. Throughout the project's engagement with the African Medical Devices Forum (AMDF), the WHO's embedded role in the Forum has prioritized capacity building on complex regulatory matters prior to addressing fundamental elements. In this role, the WHO has maintained that trainings on regulatory reliance and recognition are "confidential," recommending that MDRC training avoid this "sensitive" area. These actions are not consistent with MDRC,

4) **IMDRF, CDRH, WTO and global efforts to combat and recover from COVID-19**.

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 successful capacity building in PY3. 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	Meeting between ANSI, Pivot, and future speakers of the workshop on bioethanol to review presentations	May 2 and 9, 2022	ANSI staff and Pivot representatives
1	N/A	ARSO	Webinar#1 focusing on the introduction to Bioethanol	May 12, 2022	20 participants
1	N/A	ARSO	Meetings between ANSI and Pivot to assess webinar #1	May 13, 2022	ANSI staff and Pivot representatives
1	N/A	ARSO	Webinar#2 focusing on adjacent sectors to Bioethanol	June 16, 2022	78 participants
2	N/A	ARSO	ARSO Webinar on Good Manufacturing Practices for Cosmetics	May 9, 2022	70 participants
5	5.7	West Africa	Workshop on harmonization of petroleum standards	July 4-7 2022	20 participants
7	7.1	Indonesia	Technical Committee Meeting	June 10, 2022	6 participants (4 male/ 2 female; 3

					private, 3 NSB)
7	7.1	Indonesia	Technical Committee Meeting	June 15, 2022	45 participants (33 male/ 12 female; 1 Academic; 2 NGO; 4 National Standard Body; 25 Government; 13 Private)
8	8.2	India	Workshop 1 on water utility management standard	April 27-28 2022	51 total participants
8	8.2	India	Check in meetings after Workshop 1 on water utility management standard	May 24 and June 22, 2022	AWWA, ANSI, and India utility participants
9	9.3	Brazil	Webinar on NSF Standard 61	June 28, 2022	101 total participants, including representatives from ANSI 42 Female/ 59 Male 77 Private sector/ 24 Public sector representatives
9	9.3	Morocco	Meetings to discuss implementation of NSF Standard 60 and 61	Q2 2022	NSF and government stakeholders (Ministry of Health, NSB, Agency for Energy and the Environment), and key private stakeholders
12	12.11	Global/ LatAm	International Webinar Series event on "The Use of Self-Tests in the Fight Against COVID-19."	7 April	80 attendees 51 female, 28 male (55 private sector)
12	12.16	LatAm/ Mexico	Workshop on ISO 13485 Certification	26 May	385 attendees 273 female, 109 male, 3 undeclared (191 private sector)
12	12.12	LatAm	Summit of the Americas: Coalition for Regulatory Convergence Meeting and Joint Coalition Meeting	6-7 June	In-person: 49 attendees 24 female, 25 male

					(33 private sector) Virtual: 43 attendees 25 female, 18 male (38 private sector)
12	12.12	LatAm	Summit of the Americas: MDRC Workshop on GRP	8 June	In-Person: 27 attendees 14 female, 13 male (20 private sector) Virtual: 31 attendees 21 female, 10 male (12 private sector)
12	12.9	SEAsia/ Indonesia	Webinar on GRP and Medical Devices (1 of 2)	15 June	170 attendees 89 female, 81 male (public/private breakdown unavailable)
12	12.9	SEAsia/ Indonesia	Webinar on GRP and Medical Devices (2 of 2)	22 June	112 attendees 58 female, 54 male (public/private breakdown unavailable)

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 8 trainings to report. A breakdown of the different workshops is presented below by activity.

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

Under this activity there are two webinars that aimed at developing the NQI of partner countries in the region. Which is in line with the reporting period for Q2 2022.

- Webinar#1 focusing on the introduction to Bioethanol, on May 12, 2022
- Webinar#2 focusing on adjacent sectors to Bioethanol, on June 16, 2022

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

There is one training about the national quality infrastructure to report under this activity for this quarterly report.

A Workshops on Harmonization of Petroleum Standards was completed between July 4 and 7, 2022. The scope of this workshop extends to all four partner countries.

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

India

There is one training raising about the national quality infrastructure to report under this activity in for this quarterly report. A workshop was delivered virtually over 2 days (April 27-28).

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

There are four trainings about national quality infrastructure to report under this activity in for this quarterly report.

- **Latin America:** MDRC held two workshops on GRP during the Summit of the Americas between June 7 to 9 2022.
- **Indonesia:** On 15 and 22 June, 2022 MDRC hosted a webinar series on GRP and medical device regulation in Indonesia.

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

- Activity #2 Support for ARSO
- Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy
- Activity #6 – Africa Concrete and Building Code Adoption Initiative.[4]
- Activity #7 – Increase the Flow of WASH Services

Performance Indicator #9: Number of workshop/reserve trade mission participants (Related to Technical Barriers to Trade awareness)[5]

[4] With buy in being low in the original targeted countries the team is planning a workshop during Q3 2022 for a wider audience.

[5] Activities not listed have not selected this PI as an indicator to report on.

Under this reporting period for this performance indicator there are a total of **5** workshop to report cumulating to a total of **584 participants**. A breakdown of the different participants in said workshops is presented below by activity.

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

There is one training raising TBT awareness to report under this activity in for this quarterly report.

A Workshops on Harmonization of Petroleum Standards was completed between July 4 and 7, 2022. The scope of this workshop extends to all four partner countries.

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

India
There is one training raising TBT awareness to report under this activity in for this quarterly report. A workshop was delivered virtually over 2 days (April 27-28). 16 organizations and over 35 individuals from those organizations participated.

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

Brazil
Under this reporting period for this performance indicator for Brazil, there is a total of 1 (one) training to report (on June 28) with a total of 101 participants from the 194 registrants. The workshop was NSF/ANSI/CAN Standard 61 Training.

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

MDRC executed 4 trainings on GRP with Tier One and Two stakeholders. These trainings convened approximately 432 participants. These trainings are essential to building good regulatory capacities and addressing barriers to trade by:

- Delivering high-level presentations on GRP policy implementation;
- 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.

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

- Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops
- Activity #2 – Support for African Organization for Standardization (ARSO)

- Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards
- Activity #8 – Utility Management Standards Training for water sector utilities
- Activity #9 – Community Water Systems – Standards for safety and risk management

5. LESSONS LEARNED

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

In trying to determine the next steps for ECOWAS bioethanol workshops, Pivot is attempting continuing its effort from Q1 2022 in adapting the planning of the events with as much time in advance as possible. That is still because:

- Limited internet connectivity it would be ideal to host these sessions in person if at all possible (or ensure at least 1-2 speakers can be present physically). This would also allow for continued discussion after the meetings were concluded.
- The need 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.
- And including a topic on the existing funding opportunities at the level of US agencies; this was requested by the participants.

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

The process for the organization of in person workshops needs to be started as early as possible (including visa applications procedures), and going forward once a location for the event has been chosen and preparation for the event has started the team should not change it.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

Because of the pandemic, ACI learned that virtual meetings are a good transitory solution to in person workshops but still are not as effective.

The colonial history of African countries and the Codes used while a colony, may make it more difficult for ACI codes to be adopted.

Finally, the team is taking into account the fact that if stakeholders stop answering this likely means that there is very low appetite for the activity and therefore the team needs to adapt and seek new parties that may be more interested.

Activity #7 – Increase the Flow of WASH Services

Local manufacturing concerns about life cycle testing of faucets were resolved by providing testing on products to demonstrate pass and failure requirements.

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

The first India workshop was very insightful for learning to provide the training in a virtual workshop. Additional opportunities for feedback and interaction will be included a more frequent intervals in future workshops. It was also learned that more technical details were desired immediately in the training with less emphasis on administrative issues. The second India workshop and the first Africa workshop will be adjusted accordingly.

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

In Morocco NSF learned that our sense that in-person engagement was needed was correct as these meetings were very effective with having open exchange on the project and each stakeholder's interest. This is a strong indicator that the training should also be done in-person. Additionally, it was learned to anticipate a several year process when/if standards related to wetted contact safety are incorporated into regulation.

For Brazil, NSF learned that the virtual approach to the training was well received. With 194 registrants and 101 attendees, this was considered to be a highly attended event by other NSF's training comparisons. This also is a strong indicator of the interest within the country for standards related to water quality and safety.

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

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

The project team continues to incorporate lessons learned on hybrid in-person/virtual engagements with stakeholders. In the execution of the events alongside the Summit of the Americas, MDRC organized its first hybrid in-person trainings. For its in-person attendees, MDRC learned to effectively navigate COVID-19 protocols in addition to international travel restrictions/regulations. The project team then utilized its online capacity-building and digital resource capabilities to extend programming to a large virtual audience. Importantly, MDRC leveraged its virtual platform and Zoom licenses to enable simultaneous language interpretation for both in-person and virtual attendees. This was a critical element in the effective execution of capacity building.

In addition to the Coalition website and resource library, MDRC launched a separate site at the URL **www.standardsalliance-mdrc.org**. This site will serve as an additional avenue to disseminate project resources.

6. PLANNED ACTIVITIES FOR NEXT QUARTER,

INCLUDING UPCOMING EVENTS

Activity #	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
1	N/A	ARSO	N/A	ARSO Webinar on Bioethanol	July/ August/ September 2022	Online	TBD
5	5.3	West Africa	N/A	Introduce the group to the ASTM standardization process in advance of their visit to the December Committee meetings of ASTM Committee D02	Q3 2022	Online	TBD
6	6.2	Africa	N/A	Webinar in Africa Concrete and Building Code initiative	August 24, 2022	Online	TBD
7	7.2	Indonesia	N/A	BSN is anticipated to release a decree of formally establishing the new SNI for faucets from the Head of National Standardization Agency of Indonesia (SK Head of BSN). IAPMO will begin to build out its lab testing capabilities based on the requirements established in the new SNI.	Q3		No
8	8.3	Lesotho, Malawi, Zambia	N/A	Workshop 1 on water utility management standard in Lesotho, Malawi, Zambia	September 7 to 8, 2022	Online	TBD
8	8.3	India	N/A	Workshop 2 on water utility management standard in India	July, 20-21, 2022	Online	TBD
8	8.3	India	N/A	Workshop 3 on water	Q3 2022	In person	TBD

				utility management standard India			
8	8.3	India	N/A	Workshop 4 on water utility management standard India	December 5-6, 2022	Varanasi	TBD
9	9.3	Brazil	N/A	NSF/ANSI/CAN Standard 60 Workshop	Q3 or Q4 2022	Online	TBD
9	9.3	Morocco	N/A	finalize the development of the training materials for NSF/ANSI/CAN Standard 60 and 61 and deliver training to all relevant stakeholders	Q4 2022	In person	TBD
12	12.5	South Africa	N/A	Workshop on Good Regulatory Practices - Trade	TBD August	Virtual	Yes
12	12.5	South Africa	N/A	Workshop on Good Regulatory Practices and Good Reliance Practices – WHO Guidelines	TBD September	Virtual	Yes
12	12.5	South Africa	N/A	Workshop on Post-Market Surveillance and Market Surveillance of MDs, including IVDs	TBD September	Virtual	Yes
12	12.4	South Africa	Clinical Trials for Medical Devices	N/A	TBD September	Virtual	Yes
12	12.5	Africa	N/A	Tier One Regional Forum: relevant stakeholders from Ghana, Kenya, and South Africa (and broader region, as appropriate)	TBD September	Hybrid	Yes
12	12.10	Southeast Asia	N/A	Tier Two Regional Forum: relevant stakeholders from Indonesia and Vietnam (and broader region, as appropriate)	TBD	Virtual	Yes
12	12.9	Southeast	N/A	Tier Two in-country	TBD	Virtual /	Yes

		Asia		training for Indonesia		Hybrid	
12	12.14	COL/MX - LATAM	Emergency Use Authorization – International References	N/A	TBD	Virtual	Yes
12	12.14	COL/MX - LATAM	IMDRF – Essential Principles & Table of Content	N/A	TBD	Virtual	Yes
12	12.14	COL - LATAM	Clinical Research for MDs	N/A	TBD	Virtual	Yes
12	12.13	MX - LATAM	Software as Medical Device – International References	N/A	August	Hybrid	Yes
12	12.13	MX - LATAM	Stability Studies for medical Devices	N/A	TBD	Virtual	Yes
12	12.13	MX/Peru - LATAM	IMDRF - Labeling	N/A	TBD	Virtual	Yes
12	12.15	COL - MX - PE / LATAM	Good Reliance Practices	N/A	TBD	Virtual	Yes
12	12.15	MX – PE / LATAM	Good Regulatory Review Practices	N/A	TBD	Virtual	Yes