Standards Alliance: Phase 2

Annual Narrative Report

Year 3 July 12, 2021 to July 11, 2022

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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2 (SA2)
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:	AdvaMed, American Concrete Institute (ACI), American Water Works Association (AWWA), ASTM International, Center for Water Security Cooperation (CWSC), Ethical Apparel Africa, International Association of Plumbing and Mechanical Officials (IAPMO), NSF International
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	July 12, 2021 – July 11, 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 from the first iteration of the Standards Alliance and 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 help countries remove non-tariff barriers, and stimulate economic growth, while also preserving and expanding markets 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. ANSI's role as a coordinating body and the bridge between the private and public sectors uniquely positions the Institute to build partnerships and foster

collaborative solutions that address both national and global priorities. ANSI is also 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 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 at both the national and regional level where appropriate and to involve 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 recognized the critical role standards and conformity assessment play in advancing public health and safety during global health emergencies and obligated $3.5 million to SA2, as 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 international medical device 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 trade quality medical devices. AdvaMed—a U.S. based trade association and ANSI member—is the primary private sector partner for this project, which includes select partner countries in Latin America, Africa, and the Indo-Pacific, and overflowing impacts within those regions.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative – Year 3

This section aims at providing an overview of the main achievements that have been reached to date during the Standards Alliance Phase 2 program, with an emphasis on the current reporting year (Y3). For greater details on each year of the activities the reader may refer to the quarterly reports developed by ANSI.

During the first year of the project, the COVID-19 pandemic created new challenges for the beginning of the implementation of the Standards Alliance Phase 2. In that sense most of the work during the first year focused on finalizing and creating a strong Monitoring and Evaluation framework that would facilitate the tracking of the impact that the different activities are having on the partner countries National Quality Infrastructure, and developing the subawards for each activity in the work plan.

Year 2 of the SA2 entailed significant progress in the implementation of the COVID-19 Medical Device and Regulatory Convergence (MDRC) project and the finalization of all sub-award agreements with USAID approval. MDRC achieved substantive progress by launching the Inter-American Coalition for Regulatory Convergence (the Coalition), solidifying international partnerships with relevant government and private sectors organizations, and executing medical device and good regulatory practice trainings and high-level meetings. SA2 also began early implementation and contract approval of other sub-awards in the Water,

Sanitation, and Hygiene (WASH) and energy sectors, and support for the African Organization of Standardization (ARSO). Finally, ANSI launched new SA2 content on the website (*http://standardsalliance.ansi.org/SA2*), which will continue to be updated throughout the rest of the program.

Year 3 of the project saw the beginning of the implementation of all the activities under the Standards Alliance Phase 2 with training and other workshops being carried out across all activities. Notably the MDRC in particular, continued to make significant progress towards helping the partner countries improve their health infrastructure to combat the COVID-19 pandemic, hosting several key trainings further described later in this report.

One of the MDRC's key accomplishments during Year 3 is the Tier One Gap Analysis on Good Regulatory Practices; which is intended to be a live document that will help guide policy priorities and help increase transparency on areas to focus to further develop the National Quality Infrastructure of the partner countries. Moreover, ANSI and the MDRC team participated in the Summit of the Americas in June 2022 and contributed to the development of an MoU on Transparency for TBTs between the different participating countries, carrying out key meetings in parallel to the Summit.

Other noteworthy accomplishments during this reporting year include:

- ASTM held two successful workshops on petroleum standardization allowing for a better understanding of the ASTM standards. As an outcome of these workshops, the possible participation of the African Refiners and Distributor Association's laboratories in ASTM's Proficiency Testing Programs for petroleum going forward was proposed by ASTM.

- Promoting renewable fuel uptake in West Africa; ANSI's partner Pivot forged a working relationship with ARSO and was able to begin implementing a 5-part workshop series on Bioethanol fuels. The webinar series is currently ongoing and scheduled to be completed by year end. Expected results from these trainings are not only to increase the level of expertise in the region on using alternative fuels rather than toxic fuels like wood and charcoal that are commonly used for cooking on the African continent; but also to push forward sustainable energy consumption for a better harmonization between US and Africa's standards thus facilitating trade between the two regions.

- In the water and sanitation sectors, NSF and AWWA carried out workshops in India and Brazil, respectively. Quality of life can be reduced as a result of the burden of disease from chemical and microbiological contaminants in community and household drinking water systems. NSF Drinking Water standards establishes minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water from components used in drinking water systems and chemicals used to treat drinking water. These two activities are carrying out follow up trainings so that the NSF and AWWA standards may be used in those countries and thus help achieve better safety and health standards benefiting the local population which can then be more active in building the economy of the country.

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

Following the postponement of activities in 2020 and 2021 during the peak of the COVID-19 pandemic, Pivot continued planning events for West African member states to pave the way for regional adoption of clean cooking and transportation fuels. The team 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. A virtual platform hosted by ANSI was used to connect speakers with the conference center. The workshops featured an introduction to bioethanol, adjacent sector impacts, the importance of smart policy and standards, implementation of bioethanol projects, and a panel discussion followed by a discussion around next steps. Follow-up is continuing with participants to determine the next action steps in each country:

- Connecting relevant parties in Togo and The Gambia with ASTM and relevant standards (likely ATN and TGSB)
- Circulating access to E3050 once it is approved and encouraging review for adoption
- Connecting relevant parties in Togo and The Gambia with USGC, which mentioned a couple of programs that they could benefit from and as well as policy frameworks
- Work with ECREEE to communicate around their energy strategy and existing clean cooking frameworks

The team 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.

At the time of reporting ASTM E3050 is under review by its technical committee E48, but once it is approved, the team intends to circulate it and see how they can encourage partnerships (MoU) between the local standards organizations and ASTM to give them access to the standard. Pivot is also continuing to work with ECREEE to push out a regional fuel standard/adopt the ASTM standard as well, which would impact those countries.

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

Partner countries: Continent Wide

During Y2 of the SA2, ANSI and ARSO worked together to identify areas for collaboration, which resulted in agreement to a cosmetics training series to support the harmonization of African personal care and cosmetics standards. During Y3, the Standards Alliance Phase 2 continued to target participants in ARSO Technical Committee 40 (TC40) on cosmetics. The training supported sharing of best practices in implementing and establishing regional cosmetics frameworks based on experiences from the Gulf States region aimed to assist ARSO in the development of an African standards framework for cosmetics that

will support consumer and industry interests.

In that sense Personal Care Product Council (PCPC) and ANSI carried out three webinar aims at increasing the continent capacity around Good Manufacturing Practices for Cosmetics. One was held July 7 2021 and included 56 participants. This webinar provided a thorough overview of the suggested framework for cosmetics standards and enforcement using a case study from Saudi Arabia and the Gulf Cooperation Council (GCC) Standards Organization (GSO). The second training occurred in November 2021 and saw more participation with 65 attendees; and finally, the last workshop built on the success of the previous ones and attracted 70 participants in May 2022.

The review of different global frameworks for cosmetics led the discussion to expand upon the importance of a standard that is well-tailored to the cosmetics industry. Such a standard applies to all products within the scope of cosmetics and is based on safety, not compositional requirements. Among other questions, panelists elaborated on the GSO 1943/2021 Standard on Cosmetic Safety which is an innovative standard that functions well at different levels of capacity and is both business-enabling and ensures a high level of consumer safety. GSO 1943/2021 is applied both in countries where NSBs are responsible for cosmetics and in countries where the purview falls under Health Authorities. Panelists expressed that this eliminates most trade barriers within the GCC region as well as between the GCC region and major markets. Culminating this portion of the discussion the GSO speaker offered to collaborate more closely with ARSO based on an existing MoU to facilitate the drafting of an appropriate standard for cosmetics.

Also, during Y3, and building off of the success of Activity #1 described above with Pivot, the SA2 and ARSO agreed to carry out a 5-part web series providing awareness training geared at transitioning ARSO member countries to clean fuels. The series aims to ensure countries are knowledgeable, prepared, and supportive of bioethanol while creating an enabling environment for an emerging commodity. These webinars will be completed in Y4.

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

Partner countries: Ghana, Uganda, Zambia

The Standards Alliance's Plumbing the Legal Depths activity performs diagnostics of the existing legal, policy and institutional frameworks governing National Quality Infrastructure (NQI) related to the water, sanitation, and hygiene (WASH) sector. These diagnostics assess the enabling environment to increase access to drinking water and sanitation, support the adoption and application of international WASH standards, and enable the removal of WASH NQI barriers to trade in WASH products. Legal gaps and shortcomings will be identified, and recommendations made on how these gaps can be addressed by aligning them to international standards and best practices. Further, the findings and recommendations will be validated with stakeholders and completed reports will be disseminated widely with government agencies, creating opportunities for reform.

Following introduction of the activity and concurrence with each USAID Mission, in Year 3, 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. For example, CWSC has identified contacts at water and environmental ministries and contacts from Civil Society Organizations (CSOs), International Organizations (IOs), and nonprofits such as UNICEF, World Vision, CARE, CRS, WaterAid, amongst others.

CWSC developed general and specific interview questions for 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. Please refer to Q2 2022 Quarterly report for detailed information on stakeholder questions and potential stakeholders.

In Year 3, CWSC faced implementation challenges related to identifying the people working on these issues and to find their contact information. However, CWSC leveraged their existing contacts to identify any missing contacts or contact information.

Activity #4 Training in Good Regulatory Practices for Regulatory Impact Analysis (RIA) Teams in Government Ministries

Partner countries: Zambia

This activity was completed in Q3 2020 and in 2021, ANSI remained in contact with the Zambia Business Regulatory Review Agency (BRRA) seeking updates on the development of the proposed RIA Quality Assessment Tool. BRRA leadership requested more time to consider the suggested Tool and to examine how this tool could be used in conjunction with Zambia's current RIA framework and reporting checklists that are currently in use. ANSI will remain in contact with BRRA to track its monitoring and evaluation following the implementation of trainings that were conducted in mid-2020.

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

Partner countries: Lesotho, Malawi, Zambia

Under this activity, AWWA will conduct initial face to face and virtual workshops for the benefit of peer group cohorts drawn from the staff of water sector utilities in India and the African nations of Malawi, Zambia, and Lesotho. The effort includes not just an introduction to the benefits of the use of standards but describes best practices for the implementation of 14 AWWA Utility Management Standards at each participating water utility. Workshops will be developed and conducted through a collaboration of AWWA staff, water utility Subject Matter Experts (SMEs) and local partner ROCKBlue in Africa to tailor content for the specific regional audiences. A goal of these workshops is to promote awareness and implementation of standards, with workshop participants forming the core of a longer-term, sustainable effort to continue to expand the implementation of standards in each region.

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.

Needs assessment summary:
22 utilities in Africa responded to needs assessment surveys and provided detailed answers and feedback and showed strong interest in participating in the Africa workshop series. The survey was distributed to stakeholders in the water and wastewater industry in Lesotho, Malawi, and Zambia by AWWA's partners at RockBlue.

Responses and Demographics:

Responses were received from 22 individuals. The responses included 2 from Lesotho, 9 from Malawi, and 11 from Zambia. 20 responses were from Water/Wastewater utilities, one was from a governmental agency, and one from an academic/educational organization. Responses were primarily from management and engineering (7 from Directors/General Managers and 12 from Engineer or Operations Managers) with a few other responders (1 finance, 1 HR manager, 1 Commercial Operations, and 1 Lecturer).

Organizational information:
Of those responding, all 22 indicated they work in drinking water. 15 additionally noted working with wastewater, 4 noted working with water reuse, and 1 indicated involvement with stormwater. The populations served by the utilities responding ranged from a minimum of 16,603 up to a maximum of 1,800,000. The median population served was 500,000 and the average population 619,247.

Use of Standards and Interest in AWWA Standards:
21 out of 22 responding currently use some standards in their organization. A majority noted use of national standards from their country (Zambia Bureau of Standards, Malawi Bureau of Standard for drinking water). The World Health Organization (WHO) standards and guidelines for water were mentioned by 13 respondents, and 6 mentioned ISO standards. AWWA standards were not mentioned as currently being used, and only 3 respondents were aware of the availability of Utility Management Standards from AWWA.

In ranking their interest in the different groups of AWWA Utility Management Standards, the group on drinking water management was a clear first place for relative interest with 16 of 22 ranking this group (G100, G200, G300, G480) as their highest interest. A virtual tie for second highest interest was noted with the wastewater management standards (G510, G520) and the general utility management/business practices standards (G400, G410, G420). Security related standards were a distant fourth with water reuse standards just behind in fifth. Although water reuse was fifth, several respondents include a comment about increasing interest in this topic. Other comments provided with the rankings emphasized the relation of the standards to their core activities, and to providing sustainable water and sanitation services to the customers for the enhancement of public health.

Interest in Participating in the USAID/ANSI/AWWA Training Workshops:
22 of 22 respondents expressed their buy-in to participate in the 3 quarterly workshops, with comments noting strong interest in expanding their utility management knowledge to enhance their operations. Many noted financial challenges to continuing improvement efforts as an interest in participating, and many noted ongoing or planned engagement in continuing improvement as reasons for participating. Many respondents have access to virtual platforms for the workshops with Zoom and MS TEAMS both mentioned by a large majority. Preferred time of day varied among respondents, with the likely mid-afternoon local (southern Africa) time to account for time difference of US and Africa likely to be acceptable to most participants.

Overall, the respondents provided thoughtful and thorough comments and very well match the ideal audience for the training that AWWA had envisioned. Looking ahead, trainings will be conducted in Y4 according to the plan established by AWWA and informed by the needs assessment.

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

In Q1 2021, ANSI, ASTM International and API formally kicked-off their Harmonization of Petroleum in West Africa project. Following coordination meetings with each relevant USAID Mission, ASTM and API decided to proceed with virtual training activities for the remainder of 2021. In addition, desk research on the current use and implementation of standards in the four target countries (Cote d'Ivoire, Ghana, Nigeria, and Senegal) was conducted.

Building off of that foundation, Y3 began with the activity seeking to increase the visibility of the project with other US government stakeholders as well as gathering more buy-in from the partner countries. Indeed, ASTM and ANSI met with USG Interagency staff working on standards or TBT issues to inform them about the work the Standards Alliance is doing so that they could get more involved if relevant to their work.

Discussions with stakeholders in Nigeria were also organized and the Standards Organization of Nigeria (SON) reported that many of their standards are up for 5-year review and SON would like to adopt international standards as a replacement for many of them, and so the development of a Working Group on Refining & Specifications has begun during this last year of the project.

Earlier in the implementation year the team found out that in Cote d'Ivoire although there is a national committee on petroleum products, the country is not currently aware of, or participating in, the ECOWAS harmonization efforts; and that work to disseminate the work done in Feb 2020 by the ECOWAS Harmonization report would be important in this country. Lastly, in Ghana the Ghanaian Standards Authority (GSA) spent the early part of the year determining how they best follow the harmonization effort since their national standards were working well.

In the second part of the year the team was able to push implementation forward by organizing two key workshops around petroleum standards harmonization. The first one took place in March of 2022 where all four partner countries participated. A training was conducted for the first two days of the workshop and both ANSI and API participated virtually. On the last day laboratory tours at the Ghana Standards Authority and Verity Labs were conducted. The second workshop took place in Nigeria in parallel the Nigerian Oil and Gas Conference and Exhibition (NOG) in July of 2022. This training had 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, and 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.

Moreover, 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.

[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

Activity #6 Africa Concrete and Building Code Adoption Initiative

Partner countries: Kenya, Tanzania, Uganda

In 2021, ANSI worked with the American Concrete Institute (ACI) to develop this activity which aims to promote ACI's premier standard, ACI 318 Building Code Requirements for Structural Concrete and Commentary, which references 83 standards developed by US Standards Developing Organizations (SDOs) in select African countries. The activity was introduced to each relevant USAID Mission and achieved concurrence by the end of Y2.

Beginning in Y3, ACI developed project factsheets and marketing materials to share with the various stakeholders and early in the year started a dissemination effort in Kenya, Tanzania, and Uganda to raise the visibility of the project for all key private and public stakeholders.

Engagement with partners in the countries happened first in Kenya, where USAID eagerly scheduled in-person visits and secured virtual meetings with relevant stakeholders. The team held meetings with American companies and academia and scheduled several longer, in-depth meetings with key stakeholders (either in-person or virtually) to strengthen relationships, give stakeholders a clear understanding of ACI and the benefits of working with/joining the ACI team, and to identify a path/strategy leading to the use and adoption of ACI codes and standards. This was critical during this past year because the team quickly identified as a main challenge the fact that Kenya had announced they will be adopting Eurocodes and had already started implementation towards that end. The team then, in the second part of the year focused its efforts in Kenya in highlighting the benefits of the ACI codes and standards in an attempt to mitigate the pre-existing ties that the country already had with Europe. In that sense the team was able to confirm in March 2022 that the Institute of Engineers in Kenya (IEK) had confirmed their interest in signing an International Partner Agreement with ACI, and they would be interested in co-organizing a virtual seminar with ACI for the stakeholders in East Africa (Kenya, Tanzania and Uganda) to learn more about ACI (American Concrete Institute) and their various programs and initiatives that are available to them through the Standards Alliance 2 project. As it will be further explained below this webinar ended up not materializing.

ANSI and ACI also met early in the year with Henry Mateega, USAID's Mission Engineer in Uganda to discuss a strategy for engaging stakeholders in the construction sector as well as academia in the last quarter of 2021; but overall traction in Uganda to start the work was also limited during this reporting year with only one meeting with 8M Construction Digest taking place in January of 2022. During the meeting 8M Construction Digest did mention their interest in the activity proposed by the SA2 program and an action plan was developed. Said plan includes joining Faculty Networks to get ACI materials, work with their industry contacts to build a meeting to introduce ACI, and promote ACI in Uganda with a few articles in his magazine.

In Tanzania, the research around the interested stakeholders is still, at the end of this reporting period, at an early stage. A meeting between the USAID mission in Tanzania, ACI, and ANSI was organized in February 2022 where the USAID Mission shared the contact of potentially interested stakeholders. ANSI did attempt to reach out but so far responses have been sparse.

However, in the last quarter implementation of activities in all three countries ended up being completely stalled with the team still facing the challenge of overcoming the region's stronger ties with Europe and their willingness to adopt their standards over the ones proposed by ACI. This led to a re-evaluation and reformation of the strategy for this activity. In the beginning of Y4, ANSI

and ACI plan to submit a revised plan to USAID in order to carry forward in a more productive manner.

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 country: Indonesia

Through this project, IAPMO will work with foreign ministries, local industry and U.S. manufacturers to *Increase the Flow* of water, sanitation and hygiene (WASH) related services to Indonesia by identifying technical barriers to trade, standardizing conformity assessment practices and helping to develop much-needed supply chains of safe products. The activity achieved concurrent with the Indonesia USAID Mission in late 2021.

During Year 3, IAPMO convened several meetings to formulate the new faucet standard with BSN and related stakeholders. The draft standard was released for public comment. 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. BSN hosted meetings of the Technical Committee 77-02 to discuss and resolve the substantial comments that were received. Following the meeting, a final revised draft of the SNI was submitted to BSN for approval. Further information regarding BSN and IAPMO meetings is available in Q4 2021- Q2 2022 reports.

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

Partner country: India

Under this activity, AWWA will conduct initial face to face and virtual workshops for the benefit of peer group cohorts drawn from the staff of water sector utilities in India. The effort includes not just an introduction to the benefits of the use of standards but describes best practices for the implementation of 14 AWWA Utility Management Standards at each participating water utility. Workshops will be developed and conducted through a collaboration of AWWA staff, water utility Subject Matter Experts (SMEs) and local partners AWWA India to tailor content for the specific regional audiences. A goal of these workshops is to promote awareness and implementation of standards, with workshop participants forming the core of a longer-term, sustainable effort to continue to expand the implementation of standards in each region.

Needs Assessment Summary:

- 93 responses received (83 from utilities, 10 from other water sector professionals)
    - The utilities responding were 2/3 from Drinking Water utilities and 1/3 Wastewater utilities
    - The population covered by the utilities ranged from 5,000 people to over 20,000,000 people, with 100,000 as the median population served.
    - Most respondents reported job function as Engineering Manager/Engineering or General Manager/Executive
- 42 currently use standards as part of their work, 51 do not
    - 39 are aware of the AWWA Utility Management Standards, 54 are not
- Among the 14 AWWA Utility Management Standards the primary interest from utilities centered on 4 primary standards (core standards for treatment and distribution/collection):
    - ANSI/AWWA G100 Water Treatment Plant Operation and Management
    - ANSI/AWWA G200 Distribution System Operation and Management
    - ANSI/AWWA G510 Wastewater Treatment Plant Operations and Management
    - ANSI/AWWA G520 Wastewater Collection Systems Operations and Management
- The primary reason for interest in AWWA's training was noted as utilities lacking technical assistance in developing optimization strategies
- Most have access to virtual training platforms with Zoom by far the most frequently mentioned accessible platform (77 of 93 mentioned Zoom)
- AWWA may have some challenges with language for some participants. 44 noted English as preferred workshop language while 38 noted Hindi as preferred.

In order to develop training materials for Subject Matter Experts (SMEs), AWWA reviewed and analyzed the survey data received in order to identify specific utility management standards and developed tailored workshops to fit the needs of Indian utilities. AWWA released a Request for Proposals on Nov 22, 2021to solicit an SME to review the standards and to develop content for the workshops. The

contracts for the SMEs were finalized in Q1 2022.

After that, 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

Partner country: Brazil

This project is intended to enhance in-country quality of life as a reduction of the burden of disease from chemical and microbiological contaminants in community and household systems through the promotion of NSF Standards directly or to inform and/or strengthen existing in-country programs via education, training, and promotion of integrity/values inherent in the application of third-party, independent certification programs to NSF Standards. NSF/ANSI Standard 60, Drinking Water Treatment Chemicals – Health Effects and NSF/ANSI Standard 61, Drinking Water System Components – Health Effects shall provide the baseline for discussions with stakeholders. NSF/ANSI 61 establishes minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water from products, components, and materials used in piped drinking water systems. NSF/ANSI 60 establishes similar requirements for chemicals used to treat community drinking water supplies.

The team conducted a needs assessment to determine the guidelines and processes drinking water providers in Brazil are currently using and found the main points identified below:

The survey represented participants from both private and public entities covering a broad scope of sectors relevant to the discussion of water quality in country. All participants practice, follow or adhere to national or international standards for drinking water quality and safety in full (19) or partial (1) with many listing the Brazilian standard ABNT NBR 15784 and NSF/ANSI 61.The reported level of understanding for NSF/ANSI Standard 60 and/or NSF/ANSI Standard 61 showed nearly an equal split of those who reported to have good understanding of the standards and those who did not, with slightly higher understanding for NSF/ANSI 61. Knowledge of distribution systems and premise plumbing components yielded an overall reported understanding of 3 on a scale of 1 – 5, noting half of the participants rated themselves as higher than this average.

Several water-related public health concerns were common among those issues surveyed, with water treatment deficiency and source water quality the most reported, alongside concerns about inadequate infrastructure and water scarcity. As such, it tracks that the participants cited the need for more investment in infrastructure, capacity building, regulation and knowledge and expertise.

There was much agreement among the participants that the biggest barriers to trade (domestic and international) for their business or industry is economic/high tariffs/taxes, lack of uniform practices/transparency and lack of capacity to meet demands. Additionally, very strong support for standardizing operational and manufacturing practices was reported.

Four general themes emerged to include in NSF's upcoming trainings: (1) general understanding of standards, (2) community health impact, (3) NSF Standards, and (4) business drivers. NSF developed training materials to address these interest areas, recognizing that the different audiences (manufacturers versus regulators) and tailoring the material accordingly.

During Year 3, outreach to stakeholders was related to broad dissemination of invitation to the NSF/ANSI/CAN Standard 60 and 61 scheduled training events. 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.

NSF/ANSI/CAN Standard 60 and Standard 61 represent different product types, therefore these two standards were held as two separate training events.

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 60 or 61 detailed technical overview the training was pre-recorded in Portuguese. Using platform ON24 (https://www.on24.com/) the recording was played live on June 28 (NSF 61) and October 25 (NSF 60) 2022.

MIDDLE EAST NORTH AFRICA

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

Partner country: Jordan

A sub-award with IAPMO was approved in 2021 to carry out this activity in Jordan as well as Indonesia, but through subsequent discussions with the Jordan USAID Mission, the SA2 learned that this activity would not achieve concurrence, so the work plan and budget is being updated to reflect a redirection of resources to Indonesia.

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

Partner country: Morocco

This project is intended to enhance in-country quality of life as a reduction of the burden of disease from chemical and microbiological contaminants in community and household systems through the promotion of NSF Standards directly or to inform and/or strengthen existing in-country programs via education, training, and promotion of integrity/values inherent in the application of third-party, independent certification programs to NSF Standards. NSF/ANSI Standard 60, Drinking Water Treatment Chemicals – Health Effects and NSF/ANSI Standard 61, Drinking Water System Components – Health Effects shall provide the baseline for discussions with stakeholders. NSF/ANSI 61 establishes minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water

from products, components, and materials used in piped drinking water systems. NSF/ANSI 60 establishes similar requirements for chemicals used to treat community drinking water supplies.

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.

For the Needs Assessment, NSF International held in-person meetings with representatives from Moroccan Ministry of Health, ONEE (Office National de l'Energie et de l'Envioronnement), IMANOR (Institut Marocain de Normalisation) and Redal (Veolia), occurring each individually in Rabat and Amitech Maroc, taking place in Casablanca.

The outcome of the discussions included strong support for strengthening of the safety of materials in wetted contact with drinking water. Uptake of standards in Morocco is believed to be possible through promotion of competitive market advantage, specifying in procurement tenders and, with time, adoption into Moroccan legislation. There were shared concerns related to how certification requirements would impact the cost of projects and noting of obstacles, such as raw material scarcity and of how to address competition among testing and certification bodies. It was recognized that there is increasing pressure and interest in specifying various standards for products in the market, therefore the existence of an enabling environment for standards that address drinking wetted contact material safety exists and several stakeholders sharing a proposed path for the discussion. Although these paths were outlined, all agreed that adoption under regulation would not be a quick process, anticipating would require several years.

In-person engagement was the primary activity near the end of Year 3. In addition to arranging for face-to-face meetings, to ensure best communication, an NSF member, Jérôme Logie, NSF International Global Marketing Manager, fluent in French and familiar with the country of Morocco, was identified as a useful resource for stakeholder engagement. Jérôme traveled with NSF's technical lead on the project, Wessam Al Azzeh, Manager Water EMEA, for the in-person meetings. These meetings included the Moroccan Ministry of Health, ONEE (Office National de l'Energie et de l'Envioronnement), IMANOR (Institut Marocain de Normalisation), Redal (Veolia), and Amitech Maroc. In Morocco, in-person engagement in-country allowed for completion of the Needs Assessment phase and progression to Training phase, although NSF will follow-up on those additional stakeholders recommended during the meetings.

2.3 COVID-19 Related Activities Implementation Status

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

AFRICA

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

Partner country: Ghana

During 2021, ANSI and Ethical Apparel Africa (EAA) worked to understand material and performance requirements of surgical masks that can be used in healthcare settings. This included seeking guidance to

ensure the surgical masks meet international standards. Specifically, the production set up is designed to an ISO 7 clean room standard with the product meeting at least Level 1 ASTM surgical mask standard for bacterial filtration efficiency, particulate filtration efficiency, fluid resistance to synthetic blood, and flame spread. EAA has also engaged with the Ghana FDA to ensure that local requirements will be met.

During this entire year of implementation this activity continued 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 was 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. Should this progress be implemented they will be captured in the following annual report. 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

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

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

Global

Stakeholder Engagement

Since the project's inception, MDRC has participated in a regular series of interagency coordination calls for the Standards Alliance projects. Those U.S. agencies included the U.S. Trade Representative (USTR), International Trade Agency (ITA), National Institute of Standards and Technology (NIST), U.S. Department of State, U.S. Food and Drug Administration Center for Devices and Radiological Health (FDA/CDRH), the U.S. Department of Commerce, and U.S. State Department. These meetings help increase collaboration with U.S. government stakeholders, who are important partners in the execution of MDRC trainings. They also serve as an opportunity to align on best practices in the administration of technical assistance, share information, and learn from other projects.

In all project activities, including trainings, MDRC tracks the participants and their gender identification. In this reporting year, it led outreach with project countries to understand the quantity of their existing policies, programs or measures that directly (1) promote gender equality and diversity inclusion in their organizations or sub-agencies; and/or (2) increase awareness/knowledge of the role of gender equality and diversity inclusion in their organizations or sub-agencies. However, not all government partners responded to MDRC's request for information.

Moreover, the team has used as basis for its engagement with the partner countries the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries unified under the Tier

One published this year. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. Again, this is a *live document* which will be updated throughout the remainder of the project as more input and feedback from governments and relevant stakeholders are received.

On Q3 of 2021 the Global Medical Technology Alliance's (GMTA) Regulatory Committee agreed to (1) establish a GMTA-GDA COVID-19 Workstream, thereby constituting the International Center for Emergency Regulatory Response, (2) develop COVID-19 recommendations to IMDRF, WHO, G/AHWP regarding appropriate international benchmarks, (3) support the organization of a COVID-19 Regulatory Workshop with NRAs to address pandemic/emergency elements, (4) participate in MDRC direction and implementation, (5) accept support for MDRC-Related Training, and (6) include links to the MDRC project website and any related resources on the GMTA website (when ready). To coordinate these elements, the GMTA agreed to form an MDRC advisory group with members from the Coalition, AdvaMed, MedTech Europe, Mecomed, private companies, and a standard developing organization (SDO).

Still in 2021 the team continued to work on a whole-of-government approach to operationalizing GRPs, including the appropriate use of relevant international standards. To that end the team started to implement actions to reduce the time it takes to convene appropriate parties in the context of addressing COVID-19 subjects. 'Country clusters' serve to facilitate inter-ministerial coordination, implement international treaty obligations and domestic legal obligations, and remedy bottlenecks at both Tier One and Tier Two based on the findings of the Tier One report.

Trainings and Events

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

In Q2 2022, MDRC participated in the USAID/Trade and Competitiveness Activity Webinar on Standards, Trade, and Innovation. This webinar was part of a series to promote discussion about the challenges and opportunities of the digital economy. The webinar was an opportunity for international development partners, private sector leaders, and other thought leaders to discuss the advancement of economic development in a post-COVID world. MDRC participated in a discussion on the use of international standards in trade and innovation in health-related areas such as medical devices.

Latin America

Stakeholder Engagement

The team continued its progress on the development and implementation of the Coalition. Launched in Q2 2020, the Coalition has hosted a series of hybrid and virtual meetings and capacity-building workshops. The Coalition partners with global, regional, and local project country stakeholders to advance GRP implementation and medical device regulatory convergence.

On behalf of MDRC, the Coalition led project outreach in the region and hosted a number of trainings at the Tier One and Tier Two levels. As part of those efforts, the Coalition has engaged with important

regional and global stakeholders, such as the World Health Organization (WHO), Pan American Health Organization (PAHO), Inter-American Development Bank (IDB), and World Trade Organization (WTO). Notably, during the meetings with PAHO all parties underlined again the role of GRPs and stressed the importance of facilitating the participation of all pertinent authorities and inclusion of topics relevant to those authorities.

The Coalition developed and released an online resource library through an easily-navigable website, which can be accessed here: https://interamericancoalition-medtech.org/regulatory-convergence/. This website is a tool to convene stakeholders for events, share translated recordings of trainings and capacity building exercises, and publish and disseminate resources pertaining to GRP and medical device regulatory convergence. The website was accessed by over 3,100 visits in Q3 2021, 4,400 in Q4 2021, 2,300 in Q1 2022, 4,300 in Q2 2022.

Additionally, as a member of the Americas Business Dialogue (ABD), the Coalition collaborated with the Inter-American Development Bank between November 2020 and Q2 2022 to mutually undertake a survey of GRP in Latin American project countries. The survey updated and expanded existing assessments of GRP policies in Latin American project countries. This supports MDRC work by helping improve project countries' knowledge about the value of using national quality infrastructure and increasing private sector participation in regulatory development.

In Q3 2021, MDRC met with the Pan American Standards Commission (COPANT) to gain a deeper understanding of whether COPANT has any measures or policies that promote gender equality in the organization, gender representation in standards development, or any other initiatives or polices on gender. COPANT indicated it does not. However, the organization recently engaged in an August workshop on Best Practices on Gender Inclusion and Standardization. MDRC and COPANT discussed how COPANT could issue recommended guidelines / best practices on gender inclusion for its members.

Overall throughout this reporting year, the team continued its efforts to expand relationships with key government and private stakeholders in the different partner regional partner countries under this activity, as it is furthered detailed in the relevant quarterly reports included in this timeframe.

Trainings and Events

As a member of the Americas Business Dialogue (ABD), the Coalition collaborated with the Inter-American Development Bank between November 2020 and Q2 2022 to mutually undertake a survey of GRP in Latin American project countries. The survey updated and expanded existing assessments of GRP policies in Latin American project countries. This supports MDRC work by helping improve project countries' knowledge about the value of using national quality infrastructure and increasing private sector participation in regulatory development.

Between 6-8 June 2022, 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. These events convened high-level representatives from industry, government, and civil society, including project country ministries from Brazil, Colombia, Mexico, and Peru responsible for international GRP implementation and alignment. MDRC and Coalition programming was structured to enable those Tier One representatives to engage with key government ministers and industry stakeholders from across 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. MDRC through the Coalition continued this work by hosting 9 capacity building workshops at the regional level, which details can be reviewed in the relevant quarterly reports that are covered under this reporting year.

Finally, MDRC through the Coalition continued its work at the country level. It hosted 5 workshops in Colombia, conducted 5 trainings in Mexico, executed 1 workshop in Peru, and supported workshops in Brazil.

BRAZIL:

The Coalition member ABIIS held a two-day workshop with ANVISA on GRP and medical device regulatory convergence. The event was executed with the support of the Coalition and convened more than 400 attendees. Participants included the ABNT-designated entities for Brazilian medical device technical committees CB-26 (ABIMO) and CB-26 (SBAC).

COLOMBIA:

All the relevant training in Colombia took place at the beginning of this reporting year, from July to September of 2021.

- **GRPs Training**: MDRC conducted a training on GRPs for Colombian government stakeholders and members of the private sector. The training helps develop a basic set of capacities among these stakeholders to advance GRPs in Colombia. Attending government stakeholders included MinCIT, Ministry of Health, DNP, and INVIMA. In addition to ANDI, the National Business Association of Colombia, participants from 34 companies attended.

- **Ex-Post Analysis**: MDRC conducted a training on Ex-Post Evaluation for Colombian government and private sector stakeholders. This training will enable its participants to pursue updates to Colombian regulation affecting medical devices and IVDs. Government stakeholders included MinCIT, Ministry of Health, DNP, and INVIMA. In addition to ANDI, participants from 34 companies attended.

- **U.S. FDA Regulations for MDs – Colombia:** MDRC conducted a training for Colombian regulators and private sector stakeholders on items related to Ex-Post Analysis. The U.S. FDA provided an overview of medical device and IVD regulations. Attending government stakeholders include the Ministry of Health, DNP, and INVIMA.

- **Joint MDRC – DNP Workshop on GRP**: Problem Tree Methodology: MDRC partnered with Colombia's DNP to organize a workshop on the construction of "Problem Trees," a GRP tool that is utilized among MDRC project groups both for Regulatory Impact Assessment (RIA) and ex-post evaluation. The workshop convened participants from the Ministry of Health, INVIMA, DNP, and the private sector.

- **Joint Ministry of Health – MDRC Workshop on RIA Problem Trees**: MDRC

organized a workshop in coordination with Ministry of Health for government and private sector stakeholders in Colombia. Stakeholders shared their experience developing a "Problem Tree," a critical component under the RIA process for GMPs for Medical Devices. This workshop convened participants from the Ministry of Health, INVIMA, the DNP, and the private sector

MEXICO:

During this year, in Mexico, the team implemented a four-part webinar on GRPs for the Medical Devices sector. The details of those webinars are included in the quarterly reports and are also mentioned in section 3 of this report.

Additionally, the team carried a key training 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.

PERU:

The team organized a workshop in Peru to provide training for private sector and government stakeholders on the local and global obligations and benefits of implementing GRPs. Those government attendees included representatives from MinCETUR, PMC, DIGEMID, Ministry of Health, DIGEMID, and U.S. FDA. From academia, attendees included the Universidad Peruana Cayetano Heredia, Universidad Nacional de San Marcos, and the Universidad Pontificia Católica del Perú. In addition, over 250 companies from 8 different countries (Argentina, Brazil, Colombia, Spain, Mexico, Panama, Peru, United States) participated in this workshop.

Other Major Developments:

In Q3 2021, USAID approved the Government of Colombia and MDRC's request to establish a dedicated project Liaison to Colombia to coordinate project implementation among local stakeholders. Those local stakeholders include, but are not limited to, the National Planning Department (DNP), Ministry of Health, Ministry of Commerce, Industry and Tourism (MinCIT), Colombia National Food and Drug Surveillance Institute (INVIMA), and the National Business Association of Colombia (ANDI). Following approval, MDRC's Colombia Liaison rapidly advanced project objectives in the country. Among additional workstreams to build regulatory capacity and ensure compliance with international obligations, the Liaison continues to coordinate the following alongside local partners:

- 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 Manufacturing Practices

These workstreams include the collection of data, development of resources, seeking internal and external stakeholder input, and publication – among many other aspects. Through these processes, MDRC is continually reinforcing the importance of leveraging international standards and developing National Quality Infrastructure.

Africa

Stakeholder Engagement:

In the early months of this reporting year the team finally obtained Mission concurrence to start implementation in Kenya, which with the concurrence obtained in Ghana and South Africa the year prior finally allowed MDRC to carry out activities in all regional partner countries.

GHANA:

MDRC received a response from the focal point in mid-December and held an introductory meeting with the Ministry in January 2022. The Ministry was vocally supportive of MDRC and requested additional materials to review and aid its decision to formally partner with the project. In February 2022 MDRC provided the Ministry of Health with an Implementation Overview and Proposal for collaboration on the project. The Ministry confirmed it shared this document with its wider team for review. MDRC was not able to connect with the Ministry of Health in the subsequent months.

The team also partnered with the U.S. Department of Commerce, Department of State, Office of the U.S. Trade Representative, and other local partners to extend additional outreach to the Ministry of Trade and Ministry of Health. In June 2022, USG partners in Ghana informed MDRC that U.S. Deputy Secretary of Commerce Graves met with Ghana's Deputy Minister of Trade and Industry Herbert Krapa. In that meeting, Graves raised the need for cooperation on several standards-related issues, including the MDRC initiative. Thereafter, the partners shared MDRC informational resources and Tier One Working Document with both Ministries. The Ministry of Trade indicated interest in MDRC and desire to work with the project. MDRC will work to meet with the Ministry in Q3 2022.

KENYA:

MDRC conducted outreach in Kenya in Q4 2021 (see Implementation Challenges). Thereafter, MDRC worked with the Pharmacy and Poisons Board (PPB) to formally develop a dedicated Tier Two workstream. In Q2 2022, MDRC and PPB developed an MOU to formalize their partnership. As of the end of PY2, this MOU has not been fully executed due to delays within PPB – including bandwidth constraints resulting from PPB's undergoing the WHO Global Benchmarking Tool Plus (GBT+) assessment (see Implementation Challenges).

Following meetings with the Kenyan Bureau of Standards (KEBS) and the Kenyan Customs and Border Control Department, KEBS formally agreed to partner with MDRC in February 2022. MDRC has partnered with the U.S. Department of Commerce, Office of the U.S. Trade Representative, and other local partners to extend outreach to the Ministry of Trade.

SOUTH AFRICA

The Mission in South Africa granted concurrence to MDRC in April 2021. In order to synchronize messaging with Ghana and Kenya, MDRC opted to delay formal outreach until July when all three project countries secured Mission concurrence. After issuing formal outreach letters in August 2021, the South African Health Products Regulatory Authority (SAHPRA) formally agreed to begin workstream development in December 2021. Following regular meetings in Q1-Q2 2022, MDRC and SAHPRA crafted a tentative schedule of trainings in the project country. However, SAHPRA opted to not proceed with the workstream until both parties could sign a Terms of Reference. These Terms remain under review by SAHPRA at the time of this report closing.

MDRC has partnered with the U.S. Department of Commerce, Office of the U.S. Trade Representative,

and other local partners such as the South African Medical Device Industry Association (SAMED) to extend outreach to Tier One ministries in South Africa. Subsequently, MDRC introduced the project to DTIC and SABS on 21 April, 2022.

Trainings and Events

Between Q4 2021 and Q2 2022, MDRC attended regular meetings with the AMDF and its counterparts at the WHO and AUDA-NEPAD. MDRC and the other stakeholders continuously discussed how to advance MDRC objectives through joint regional trainings and in the AMDF Strategic Plan 2022-2027 and 2022 Work Plan.

MDRC worked with representatives from the Department of State, Department of Commerce, and USAID in D.C. and Accra to drive engagement with the African Continental Free Trade Area (AfCFTA) Secretariat. MDRC sought to leverage international trade obligations (such as those in the AfCFTA and WTO TBT agreements) from the continental level in country-level activities. On MDRC's behalf, USG stakeholders conducted outreach with the AfCFTA Secretariat on multiple occasions. However, given the limited bandwidth of the Secretariat, MDRC has not been able to introduce the project to the AfCFTA.

Under Year 3 of SA2, MDRC collaborates with the U.S. Department of Commerce, Office of the U.S. Trade Representative, U.S. FDA/CDRH, and other U.S. government partners in local and regional engagement. Commerce's International Trade Administration (ITA), supported MDRC by (1) facilitating country-specific outreach and initial engagement with relevant government stakeholders, (2) subsequent country-specific coordination to implement MDRC on a local level, and (3) regional-level cooperation and engagement.

Other Major Developments:

MDRC finalized its Stakeholder Mapping Reports in Q1 2022. These reports outline Tier One, Two, and regional (where appropriate) stakeholders in Indonesia, Vietnam, SE Asia, Ghana, South Africa, and Kenya. They have been reviewed by the same industry associations, USAID Missions, and US agencies, such as the International Trade Administration (ITA). Like the Tier One Working Document, these may be updated as necessary through the remainder of the project.

Indo-Pacific

Stakeholder Engagement:

MDRC successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam and Indonesia.

INDONESIA:

In Q3-4 2021, MDRC leveraged meetings with private sector actors and government partners, including in the U.S. FCS and U.S. Embassy in Singapore, to establish contact with local government stakeholders. Following an in-person conversation in Washington, DC, in October 2021 MDRC sent an email to the Indonesian Minister of Health Budi Sadikin and his special assistant to seek his support to assign relevant senior officials to coordinate with MDRC. In November 2021, the Indonesian Embassy in DC agreed to assist MDRC in following up with the Ministry of Health. As a result, the Ministry contacted the U.S. Mission in Indonesia regarding MDRC. In December 2021, MDRC introduced the project to the Ministry

of Health. MDRC's workstream with the Ministry was formally approved in April 2022. Between April and June 2022, MDRC and the Ministry planned the execution of a two-part webinar series on GRP and medical device regulation. See Trainings and Events, and Workshops and Trainings for details.

VIETNAM:

Throughout Year 3 of the project, the team worked extensively to develop Tier Two workstreams in Vietnam. In Q3 2021, met with the Government of Vietnam's Department of Medical Equipment and Construction (DMEC), the country's medical device regulatory authority. Between Q3 2021 and Q2 2022, DMEC and MDRC held regular meetings to formalize their workstream. In Q2 2022, DMEC leadership approved the MDRC official implementation workplan. However, MDRC is awaiting final approval by the Ministry of Health's Department of International Cooperation (DIC) and Legal Department. See Implementation Challenges.

Trainings and Events

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. In Q2 2022, at ITA's suggestion, the MDRC team prepared a concept note with Tier One and Two topics for inclusion in the regional event. Upon review of the concept note, the ASEAN Secretariat (ASEC) shared that it prefers MDRC's request for potential engagement with the ACCSQ to be raised under official G2G discussions. ITA and MDRC agreed to pursue this strategy in Q2-3 2022.

In August 2021, AdvaMed attended the Asia Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SOM3 SCSC) meetings as an accredited U.S. delegate to ensure MDRC implementational alignment with related regional activity. Those meetings include the SCSC Workshop on GRPs as well as the SCSC Plenary. AdvaMed noted the participation of the MDRC project country authorities in the meetings.

On 15 June 2022, MDRC hosted the first of a 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 2022, 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.

Other Major Developments:

As mentioned in the section above the team finalized its Stakeholder Mapping Reports in Q1 2022 which covers the Indo-Pacific region.

2.4 Implementation Challenges

This section aims at highlighting challenges that relate to the content of the activities and difficulties in

implementing them with the partner countries. It does not mention logistical issues arising from remote work or communication with the local government stakeholders. However, it is relevant to underline that certain activities have encountered those types of challenges and they have been highlighted in the relevant quarterly reports.

Activity #6 – Africa Concrete and Building Code Adoption Initiative

The buy-in for American standards related to the production of concrete has been a challenge since the inception of this activity during the first year of the project. Indeed, the East African countries that have partnered with ACI on this project still have strong ties with European countries given the more intertwined history they share and as such they have been more receptive to the adoption of their standards over ACI's.

Activity #7 – Increase the Flow of WASH Services

In Indonesia, the life cycle testing requirement has been very stringent on local manufacturers. A resolution between the manufacturer and the technical committee to reduce the life cycle testing requirements to 100,000 cycles has been reached in the second quarter of 2022 which should alleviate this challenge going forward.

Additionally, IAPMO faced the following implementation challenges during Year 3:

1. The update of the previous existing standard was quite challenging since the required testing parameters were very limited as well as the acceptance criteria for each parameter was quite loose.
2. The number of Small and Medium Enterprises (SME) from local regions in Indonesia, which participate mainly through the Association of Valve Industry. They have reported limitations on both technology and resources.

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

Both in India and in the African partner countries participation agreements were developed and distributed. However, AWWA discovered that by removing the requirement to sign the agreements that barriers to participation were removed due to not needing to circulate them more broadly through the utility management which would result in longer delays. As such after the first quarter of 2021 AWWA no longer requested those agreements and has been able to solve the issues created by the agreements.

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

Since the beginning of implementation of this activity in the first year of the Standards Alliance Phase 2 IMANOR has 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.

NSF continues to hold meetings with IMANOR to argue that 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.

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

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.

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

Mission concurrence

Overcoming project implementation delays related to local USAID Mission concurrence across a number of project countries was an important challenge. In some cases, the time between initial consultation with a USAID Mission and formal concurrence was several months. These delays prevented MDRC from engaging with local stakeholders to advance project outputs. For example, the Mission in Kenya issued concurrence at the end of July 2021 after months of outreach by MDRC. Thereafter, the Mission did not approve MDRC project outreach letters in Kenya, despite multiple requests by the project, delaying the distribution of the letters for 6 months. Additionally, 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.

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, 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.

3. Workshops and trainings conducted

As the Annual Report aims at providing an overview of all the workshops carried out since the inception of the Standards Alliance Phase 2, the table below will reflect a cumulative list of all trainings held with the most recent trainings first.

Activity #	Sub activity #	Country	Trainings/ Workshop	Date	Participants
1	N/A	ARSO	ARSO Webinar on Bioethanol	July 2022	
8	8.3	India	Workshop 2 on water utility management standard	20-21 July, 2022	
5	5.7	West Africa	Workshop on harmonization of petroleum standards	4-7 July 2022	20 participants
9	9.3	Brazil	Webinar on NSF Standard 61	28 June, 2022	101 total participants, including representatives from ANSI 42 Female/ 59 Male

					77 Private sector/ 24 Public sector representatives
12	12.9	SEAsia/ Indonesia	Webinar on GRP and Medical Devices (2 of 2)	22 June, 2022	112 attendees 58 female, 54 male (public/private breakdown unavailable)
12	12.9	SEAsia/ Indonesia	Webinar on GRP and Medical Devices (1 of 2)	15 June, 2022	170 attendees 89 female, 81 male (public/private breakdown unavailable)
1	N/A	ARSO	Webinar#2 focusing on adjacent sectors to Bioethanol	16 June, 2022	78 participants
12	12.12	LatAm	Summit of the Americas: MDRC Workshop on GRP	8 June, 2022	In-Person: 27 attendees 14 female, 13 male (20 private sector) Virtual: 31 attendees 21 female, 10 male (12 private sector)
12	12.12	LatAm	Summit of the Americas: Coalition for Regulatory Convergence Meeting and Joint Coalition Meeting	6-7 June, 2022	In-person: 49 attendees 24 female, 25 male (33 private sector) Virtual: 43 attendees 25 female, 18 male (38 private sector)
12	12.16	LatAm/ Mexico	Workshop on ISO 13485 Certification	26 May, 2022	385 attendees 273 female, 109 male, 3 undeclared (191 private sector)
1	N/A	ARSO	Webinar#1 focusing on the introduction to Bioethanol	12 May, 2022	20 participants
2	N/A	ARSO	ARSO Webinar on Good Manufacturing Practices for Cosmetics	9 May, 2022	70 participants
8	8.2	India	Workshop 1 on water utility management standard	27-28 April 2022	51 total participants
12	12.11	Global/ LatAm	International Webinar Series event on "The Use of Self-Tests in the Fight Against COVID-19."	7 April, 2022	80 attendees 51 female, 28 male (55 private sector)
12	12.1	Global	International Webinar Series – "The use of Self tests in the fight	31 March, 2022	161 total participants 50 Male/ 108 female/ 3 undeclared

			against COVID-19"		38 public/123 private stakeholders
1	N/A	The Gambia	ECOWAS bioethanol workshops	21-22 March, 2022	29 total participants 17 Male/ 12 Female 16 public/ 13 private stakeholders
1	N/A	Togo	ECOWAS bioethanol workshops	17-18 March, 2022	35 total participants 30 Male/ 5 Female 17 public/ 18 private stakeholders
12	12.1	Global	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 4)	17 March, 2022	181 total participants 51 Male/ 129 female/ 1 undeclared 106 public/75 private stakeholders
12	12.1	Global	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 3)	10 March, 2022	167 total participants 35 Male/ 130 female/ 2 undeclared 111 public/56 private stakeholders
12	12.1	Global	MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment (Session 2)	3 March, 2022	237 total participants 62 Male/ 161 female/ 3 undeclared 141 public/96 private stakeholders
5	5.3	Côte d'Ivoire, Ghana, Nigeria, Senegal	Workshop on Petroleum Standards	1-3 March, 2022	8 total participants 4 Male/ 4 Female 5 public/ 3 private stakeholders
12	12.1	Global	MDRC-FDA Medical Devices Webinar Series on Unique Device Identification (Session 2)	27 January, 2022	237 total participants 54 Male/ 180 female/ 3 undeclared 67public/170 private stakeholders
12	12.1	Global	MDRC-FDA Medical Devices Webinar Series on Unique Device Identification (Session 1)	20 January, 2022	203 total participants 44 Male/ 158 female/ 3 undeclared 61public/142 private stakeholders
12	12.11	Latin America	Joint MDRC-FDA Webinar on Utilization of International Standards and Conformity Assessment	7 December 2021	130 participants 97 female, 33 male (62 private sector)
12	12.11	Latin America	ALADDIV and CBDL's XI International Workshop – "Quality	6-7 December	Dec 6: 176 participants 108 female, 67 male, 1 undeclared

			Assured and Accessible Diagnostic Tests for Public Health Programs"	2021	(79 private sector) Dec 7: 119 participants 87 female, 32 male (57 private sector)
12	12.16	Mexico	Webinar4 on GRPs in Health Regulations – COFEPRIS	24 November 2021	153 participants 104 female, 48 male, 1 undeclared (131 private sector)
2	N/A	ARSO	ARSO Webinar on Good Manufacturing Practices for Cosmetics	23 November 2021	65 Participants
12	12.11	Latin America	ABIIS Medical Devices Webinar – Regulation, Advances, and Perspectives	22-23 November 2021	445 participants
12	12.16	Mexico	Webinar3 on GRPs in Health Regulations – COFEPRIS	17 November 2021	165 participants 118 female, 46 male, 1 undeclared (113 private sector)
12	12.16	Mexico	Webinar2 on GRPs in Health Regulations – COFEPRIS	10 November 2021	183 participants 130 female, 53 male (131 industry)
12	12.16	Mexico	Webinar1 on GRPs in Health Regulations – COFEPRIS	27 October 2021	267 participants 194 female, 70 male, 3 undeclared (192 private sector)
12	12.16	Peru	Workshop on GRPs	7-8 September 2021	540 participants 7Sep: 260 female, 68 male, 2 N/A (264 private sector) 8Sep: 160 female, 44 male (204 private sector)
12	12.16	Colombia	Workshop on RIA Problem Trees	6 September 2021	56 Participants 46 female, 10 male (41 private sector)
12	12.16	Colombia	Workshop on GRP: Problem Tree Methodology	26 August 2026	64 participants 56 female, 9 male (43 Private sector)
12	12.16	Colombia	Workshop on Ex-Post Analysis	27 July 2021	81 participants 66 female, 15 male (56 private sector)
12	12.16	Colombia	Workshop on GRPs	23 July 2021	124 Colombia 100 female, 24 male (59 Private Sector)

2	N/A	ARSO	ARSO Webinar on Good Manufacturing Practices for Cosmetics	7 July 2021	56 Participants
12	12.6	Africa	Webinar 2 on GRPs, TBT, and their impacts on the medical technology sector during COVID-19.	24 June 2021	16 participants 11 female, 5 male (all private)
12	12.6	Africa	Webinar 1 on GRPs, TBT, and their impacts on the medical technology sector during COVID-19.	17 June 2021	15 participants 10 female, 5 male (all private)
12	12.11	Latin America	Webinar series with USFDA on ISO 13485 and Medical Device Single Audit Program (MDSAP) outcomes utilization for regulatory purposes	2 to 17 June 2021	400 Participants: 15 National Regulatory Authorities (NRAs)
12	12.1	Brazil	Workshop on GRPs and International Trade	16-17 March 2021	184 Participants
12	12.16	Mexico	GRPs Training	12 November 2020	

4. SUCCESS STORIES

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

Prior to this project, opportunities of collaboration with ARSO were limited to cosmetic standards. Through this engagement, new areas of collaboration for technical assistance were identified and have been expanded to cover international standards for clean renewable fuels with potential impact on the entire African continent.

This demonstrates success for the ANSI-ARSO collaboration because ARSO saw value in the partnership and recognized mutual benefit from developing new areas of work to push forward better energy standards in the region, which when implemented can help the harmonization between US and regional regulations and thus cross regional trade.

As an initial step, ANSI, PIVOT and ARSO agreed to develop a five-part virtual training, scheduled to end in September 2022 with the objective of increasing expertise around alternative fuel in the continent. The expected results is to push the energy transition forward in the continent towards greener alternatives. This will be a success for better safety of the local population and the environment which are stated key

objectives of the USG. The webinar series with ARSO will be completed only with private sector contributions.

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

Through the technical assistance ASTM has clearly established with all participants that the goal is not to debate the ECOWAS Commission decisions on Fuel and Vehicle Emission Standards Harmonization, but rather to encourage the standards bodies and testing laboratories to use harmonized testing protocols that are up to date and fit for purpose in the ECOWAS region. The experts in the SA2 activity continue to examine the commonalities and differences in testing across West Africa and develop a deeper understanding of the technical aspects of the ASTM standards. As a result, the participants are gaining more expertise on the benefits of harmonized standards and the positive impacts this can have on trade. They have also reviewed relevant ASTM standards that could be used as a technical benchmark or adopted as national or regional standards. Participants have broadly discussed topics on good regulatory practices and TBT, as well as gained direct access to ASTM technical committees beyond just those workshops. This has helped advance the governments' goal of playing a more proactive role in identifying potential areas of divergence in international norms, which can in future years of the project help eliminate potential barriers to trade that US companies have in the region or increase the transparency of the business climate.

Activity #7 – Increase the Flow of WASH Services

Since Q4 2021, IAPMO has been working with BSN (Indonesia's National Standard Body) to revise an out-of-date SNI (Indonesian National Standard) related to water faucet products: SNI 03-0122-1998. On July 18, 2022, the updated standard was published. As part of the update, the title and scope of the standard was expanded. The title for the updated SNI is "Supply Fittings For Domestic Use." Domestic use includes drinking, bathing, washing and other household activities. The scope of products covered by this standard are bath supply fittings, lavatory and bidet supply fittings, clothes washer supply fittings, kitchen supply fittings, sink supply fittings, lawn faucets, shower heads, hand showers, body sprays and supply stops.

The formulation of this standard was carried out by the Technical Committee 77-02 (downstream metal products). Considering the challenges of in-person meetings in Indonesia, IAPMO and BSN worked strategically to develop, draft, and publish the standard on schedule. As the standard was recently adopted in September 2022, it is difficult to provide an assessment on the actual impact. However, the potential impact demand for plumbing products in Indonesia in 2019 was estimated to be valued at $820 million with it projected to grow over the next 10 years. IAPMO's goal is to have the standard mandated by the national government for all applications as opposed to keeping it voluntary or making it a requirement for just public buildings.

The possibility of a mandate will shape the full impact of this standard initially. IAPMO historically looks at this through the export lens vs. the lives changed. As the 4th largest country by population in the world, any movement to improve the quality of water taps and faucets (e.g. remove lead and other contaminants from leaching, improve water efficiency, improve product reliability, etc.) will have a huge impact on that population.

Using IAPMO's history with the Standards Alliance as a guide, the first SA project generated more than $15 million in exports, which represents $50 in exports for every $1 dollar invested by USAID in the program. This project continues to have an impact. During the four years that IAPMO actively engaged on the program activities (2013-2017), average U.S. exports grew by 50%. Since IAPMO's project there

was completed until the time of the beginning of our new project, average U.S. exports have grown by 258%.

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

Under this activity ANSI and MDRC aimed at working towards increasing the transparency and predictability of partner governments' regulatory ecosystems for medical devices, aligning them with international standards, and improving their overall National Quality Infrastructure. While this is the primary goal of this activity, the project also seeks to ensure gender representation in its events, training, capacity building exercises, and speaking roles as part of a larger effort to address gender-based issues such as representation in policy making and technical work.

The MDRC has advanced the two points mentioned abovein the implementation of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition) and its programming. The Coalition's Technical Secretariat is led by the medical device industry's leading and highly experienced women that are experts in the fields of medical technology, global strategy, and regulatory affairs.

Over twenty women lead MDRC's efforts as part of the AdvaMed MDRC Core Team, the AdvaMed – MDRC Support team, the AdvaMed MDRC Steering Group (Global) & AdvaMed Global Harmonization Working Group, the AdvaMed MDRC Steering Group (Regional), women in leadership within ANSI, and others involved in the effort against COVID-19. MDRC recognizes the critical and central role women should play in the response and recovery to COVID-19. MDRC will continue to emphasize and track women's representation in its activities and general policy making and technical work across Latin America, the Indo-Pacific and Africa.

Another important milestone took place alongside the IX Summit of the Americas, MDRC through the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (the Coalition) convened high-level representatives from industry, government, and civil society for the first time to advance regional GRP implementation across the Americas.. During the meetings carried out alongside the Summit experts:

- Delivered high-level presentations of ongoing GRP policy implementation within each country and exchanged best practices;
- Participated in in-depth examinations of work being conducted in each MDRC project country to implement GRPs, including timelines and plans for future implementation;
- Explored efforts to document GRP implementation within pilot project regulatory agencies; and
- Facilitated long-term GRP collaboration among the countries.