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American National Standards Institute

Standards Alliance: Phase 2

Annual Work Plan

Year 4 July 12, 2022 to July 11, 2023

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I. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date And End Date:	July 12, 2019 – July 11, 2026
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of 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, Mexico, Peru, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Work Plan Period:	Year 4 – July 12, 2022 – July 11, 2023

I.1 PROGRAM PURPOSE AND OBJECTIVES

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

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

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S.

global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. Because of ANSI's unique role as a coordinating body and a bridge between the private and public sectors, the Institute can build partnerships and foster collaborative solutions for national and global priorities. And ANSI is a membership organization, providing members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI also promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

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

SA2 Focus on Medical Devices to Support COVID-19 Response

In June 2020, USAID further recognized the critical role of standards and conformity assessment in supporting public health and safety through an obligation of \$3.5 million to the SA2, which is part of the more than \$20 billion that the United States has committed in assistance for the global COVID-19 response. This SA2 project will promote regulatory convergence in the context of COVID-19, good regulatory practice (GRP), and the adherence and adoption of medical device international standards. These objectives will also establish an efficient medical device regulatory environment and framework that will facilitate the COVID-19 response and diminish technical barriers to trade—thus promoting trade of medical devices. AdvaMed—a U.S. based trade association and ANSI member—will be the primary private sector partner of the project, and there will be select partner countries in Latin America, Africa, and Southeast Asia, with overflowing impacts within those regions.

2. ACTIVITY PLAN

2.1 SUMMARY OF THIRD YEAR (JULY 12, 2021 – JULY 11, 2022)

The SA2 made significant progress in project implementation in Year 3. ANSI worked with USAID, partner countries, private sector partners, USAID Missions, and additional stakeholders to finalize all subawards with USAID approval. In addition, the SA2 COVID-19 response project—the Medical Device Regulatory Convergence Project (MDRC) — reached another milestone with the development of the Tier One Good Regulatory Practice (GRP) gap analysis report which will continue to be updated throughout the life of the project. It also continued stakeholder mapping, the work at the Inter-American Coalition for Regulatory Convergence (and participated in the Summit of the Americas), and trainings and webinars that have cumulatively reached

approximately 2,000 participants. Internally, ANSI has also finalized the program management toolkit and has launched the redesigned SA2 website.

In addition, the methodology for the target definition for all indicators was established. As a result of delays brought on by the COVID-19 pandemic, the ANSI team postponed in-person country scoping needs assessments which were planned to begin in Latin America, Africa, and the Middle East. Instead, ANSI decided to move forward with conducting virtual needs assessments with partner countries and collected baseline data electronically where possible. ANSI completed desk review of available information and utilized conference calls with relevant in-country contacts to go over the missing information. The needs assessment will benefit from program updates and reporting during Year 4.

ANSI anticipates that Year 4 will be extremely productive as the subaward activities begin in earnest. The SA2 has become increasingly resilient to COVID-19 travel and meeting restrictions and has adapted work plans to hold events in a hybrid form, with restrictions due to the pandemic easing up. Nevertheless, ANSI will continue to track COVID-19 developments and prioritize public safety when considering potential events in Year 4.

2.2 LIST OF ACTIVITIES FOR YEAR 4 – NON-COVID-19 RELATED

This section includes descriptions of the SA2 activities planned for Year 4 that are not supported by COVID-19 funds. Activities are organized by geographic region and then development objective¹. A table summarizing all SA2 activities for Year 4 follows section 2.3.

GLOBAL

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

Activity #13 (new) – Support for critical minerals standardization coordination

Private sector partners: TBD

Description: In March 2021, ISO/TMB and ISO Council approved the establishment of the Strategic Advisory Group (SAG) on Critical Minerals. The group's mandate was agreed as follows:

Undertake an analysis of existing and potential standardization work in the area of critical minerals from the point of initial extraction (mining and production of raw materials), and processing steps through to pre-cursor materials; and make recommendations to the TMB in this regard.

ANSI, as the U.S. representative to ISO and an active member of ISO/TMB and ISO Council, participates in the SAG and coordinates U.S. stakeholder input through a virtual Technical Advisory Group ("VTAG"). The SAG on Critical Minerals recently provided a report of its

¹ For a full description of SA2 development objectives and the Results Framework, please consult the SA2 Monitoring, Evaluation, and Learning Plan (latest version dated: August 8, 2020)

recommendations to the ISO/TMB. The SA2 will support the VTAG and the work of the SAG on Critical Minerals through activities such as:

- Conducting awareness building to expand the stakeholders represented in the VTAG to further bolster U.S. input and/or leadership in the SAG, thereby influencing outputs at the international level.
- With the input of the VTAG, support activities recommended by the SAG as next steps including dialogue with other ISO members in support of any new standards proposed or developed; training or awareness-building activities that would enable developing countries to participate in standards development for critical minerals.
- Coordinate within the U.S. stakeholder group including U.S. government agencies to align future work within ISO with U.S. strategy on critical minerals.

The following Performance Indicators will be applicable in Activity #13:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure

PI#3 Number of new international standards activities in a country participates

PI#4 Number of international standards adopted or referenced by partner country

PI#7 Number of participants in national technical committees

PI#9 Number of workshops/ reserve trade mission participants

PI#16 Number of measures implemented to promote gender equality

Expected results: Expand the U.S. stakeholder group that participates in the ISO SAG, thereby facilitating more robust U.S. input into the international results, while also facilitating U.S. leadership of SAG recommendations and future international standardization around critical minerals.

AFRICA

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

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

Private sector partner: Garner Advisors with support from POET, U.S. Grains Council, Growth Energy, Kristy Moore Consulting, ProExporter Network, Clean Cookstove Alliance, CLASP, Cornell University, Berkeley Air Monitoring, and Dalberg Advisors.

Partner countries for Year 4: West Africa

Description: This project will support national and regional workshops to enhance the understanding and uptake of international standards for clean renewable fuels across West Africa. Garner Advisors and a group of private sector partners will coordinate with the Economic Community of West African States (ECOWAS) Center for Renewable Energy and Energy Efficiency (ECREEE) to create momentum for clean fuel standards in order to galvanize further support for clean renewable fuels across the region. This event aims to provide a background on

key clean fuel standards, particularly biofuels standards, which can be utilized locally and regionally to meet energy, climate, health, and economic goals.

Out of the effort to promote renewable fuel in West Africa, Pivot has also undertaken a working relationship with ARSO to also develop workshop hosted by that body on Bioethanol. The parties have agreed to develop a five-part webinar, scheduled to end in September 2022, and thus part of this activity will be covered under this workplan. The webinar series with ARSO will be completed with only non-federal contributions. Moreover, proposals have been submitted for several in-person workshops in 2023, including in Mozambique, South Africa, and Senegal; and there are plans for a hybrid workshop in Mali in September 2022.

The following Performance Indicators will be applicable in Activity #1:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure

PI#3 Number of new international standards activities in a country participates

PI#4 Number of international standards adopted or referenced by partner country

PI#8 Number of US industry WTO TBT concerns with partner countries eliminated

PI#9 Number of workshops/ reserve trade mission participants

Expected results: Through this targeted engagement, we expect ECOWAS to adopt an international ethanol standard for household energy use (based on ASTM 3050) and to adopt/adapt a regional standard for renewable transportation fuels. These outcomes will increase the ability of users in ECOWAS nations to access clean renewable fuels, while strengthening the bilateral trade relationship for renewable fuels and eliminating technical barriers in the sector.

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

Private sector partner: Personal Care Product Council (PCPC)

Partner countries for Year 4: Africa (Continent-wide)

Description: As a continuation of capacity building for the African Organization of Standardization (ARSO) and its national member bodies, the Standards Alliance and the Personal Care Product Council (PCPC) will complete the ongoing cosmetics webinar series. This series includes virtual capacity building activities to enhance ARSO member understanding of international best practices in the cosmetics sector and to encourage harmonization of a continental cosmetics framework through ARSO technical committee 40 on cosmetics. This activity is completed entirely using non-federal contributions.

The following Performance Indicators will be applicable in Activity #2:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure

PI#3 Number of new international standards activities in a country participates

PI#4 Number of international standards adopted or referenced by partner country

PI#8 Number of US industry WTO TBT concerns with partner countries eliminated

PI#9 Number of workshops/ reserve trade mission participants

Expected results: To enhance ARSO members' understanding of international best practices

around cosmetics favoring the adoption of more appropriate cosmetic standards that ensure safety of the consumer, which in-turn strengthen the sector and favor economic development. Reciprocal social-economic benefits include reduction of population's risks of illness due to sub-standard/ low quality products. They would also contribute to SDG Goal 3: *Ensure healthy lives and promote well-being for all at all ages*. Additionally, this activity will enhance U.S.-African relations, support the development of economic approaches to trade and investment across the continent aligned eliminating a major trade barrier for U.S. cosmetics industry, thus facilitating exports to the continent in that sector leading to economic growth in the region.

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

Private sector partner: Center for Water Security Cooperation (CWSC)

Partner countries for Year 4: Ghana, Uganda, and Zambia

Description: To improve NQI and support stated WASH industry needs, CWSC is conducting research on the adoption and use of international WASH-related product standards and their reference in law, regulation and policy in Ghana, Uganda, and Zambia. The research intends to analyze how existing laws create an enabling environment for NQI, how institutions have adopted/implemented standards policy and how WASH standards are referenced in law, regulation and policy. In addition, the research aims to understand how WASH standards are influenced by sector and non-sector laws, regulations and policies, identifying any potential roadblocks created by those laws that could hinder trade of quality WASH products. The research will also briefly examine workforce development, including whether industry associations have been formed and whether a skilled workforce has been institutionalized through required certification processes. Following this analysis, CWSC will provide recommendations on potential ways forward to reform and strengthen the laws, regulations and institutions governing and influencing standards in order to improve NQI.

- Activity #3.2 – Conduct in-person or virtual interviews with Ministries, regulators, National Standards Bodies, utilities, private sector partners and civil society organizations
- Activity #3.3 – Incorporate findings from deskwork and interviews into comprehensive country-level reports

The following Performance Indicators will be applicable in Activity #3 (specifically #3.3 unless stated otherwise):

PI#1 Countries have developed their National Quality Infrastructure for WASH

PI# 2 Trainings conducted about the value of using their National Quality Infrastructure (Activity #3.2)

PI# 4 Number of international standards adopted or referenced by partner country in their law

PI#5 Countries have an enabling environment for a National Quality Infrastructure

PI#15 Countries have shared their annual national standards workplans.

Expected results (in Year 4):

- Development of 3 comprehensive, country-level reports (one for each country), based on deskwork and interviews, which evaluates the national-level laws, regulations and policies governing the development, adoption and use of WASH related standards
- Development of recommendations for in-country partners for addressing shortcomings discovered in country-level reports for each country
 - Zambia: The USAID CDCS includes the utilization of quality health, water and sanitation, and social protection services. CWSC's project supports water and sanitation directives through its research and recommendations. Additionally, it aligns with Zambian Government Priorities as the government's Seventh National Development Plan highlights that investments in health, water and sanitation are required to build a healthy population and drive socio-economic development.
 - Uganda: Climate risks in Uganda are increasing competition for water resources. Additionally, as the Uganda CDC mentions, the USAID/Uganda chairs and actively participates in sector working groups, including the Water and Sanitation Donor Group which engages in a national partnership forum to conduct structured dialogue with the Government of Uganda. Information gained through research in this CWSC project can support these dialogues.
 - Ghana: This project can help support the Ghana Mission's long-term goal to assist Ghana with achieving improved accountability in the delivery of quality services in health, via the WASH sector research and recommendations CWSC compiles.
 - The law creates the foundation for achieving most if not all of the Sustainable Development Goals (SDGs). Without clear rules, it will be impossible to ensure universal access to water and sanitation and achieve SDG6 because the law defines what "safely managed" water and sanitation services are. Without clear guidance on what must be achieved and what is required by different actors as well as a clear commitment to what is necessary to achieve SDG6, then SDG6 will likely not be achieved, will take longer to achieve, or will be achieved but only in the short term. Furthermore, the adoption of laws that require the achievement of universal access to water and sanitation creates a need for WASH products in order to achieve that goal. By creating a mandate to act to achieve SDG6, and therefore a market to ensure the mandate can be achieved, economic growth will be supported and new jobs will be created in line with SDG8. Further, good water security and WASH laws, particularly if they are gender intentional, will help to achieve SDG5 and support greater gender equality by ensuring that women hold positions in governing institutions and that laws/regulations are responsive to the needs and challenges faced by women. Additionally, countries and other stakeholders can better understand how the legal framework may be hindering trade in WASH products and therefore the country's ability to accelerate access to water and sanitation services in light of the Sustainable Development Goals (SDGs), potentially leading to the changes in law and policy necessary to improve trade in international WASH products. The law first helps to create the need for WASH products. However, the law also helps to facilitate trade in WASH products. The law helps to professionalize the sector and guarantee the safety and quality of WASH products by establishing National Standards Bodies which supports the advancement of SDG8. Further, the law helps to improve the quality and safety of the infrastructure and technology used to provide water and

sanitation services. Laws, regulations and standards help to ensure that infrastructure is more resilient and sustainable by ensuring that the infrastructure can deliver safe, affordable water and sanitation services in different settings and under different circumstances (e.g. during a natural disaster), in line with SDG9.

- Two virtual sessions per country with critical stakeholder to discuss results and recommendations based on the comprehensive country level diagnostic report
- Development and dissemination of one trend report examining trends on how the law creates a commitment to increasing access to drinking water and sanitation, how the law supports the adoption and application of WASH standards, and how the law creates an enabling environment for NQI and reduces barriers to trade in international WASH products
- Greater transparency of the laws governing the adoption and use of WASH standards
- Greater transparency of the institutions responsible for developing WASH standards or whose activities influence the development of the WASH standards

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

Private sector partner: American Water Works Association (AWWA)

Partner countries for Year 4: Zambia, Malawi, and Lesotho

Description: AWWA proposes to utilize its series of 14 Utility Management Standards that focus on water utility management practices. The trainings will be tailored to stated participant needs/goals, with guidance provided for optimization of various aspects of management practices and operations. These standards 1) are applicable to utilities of all sizes and types, including potable water, wastewater and reclaimed water utilities, 2) can be implemented without major capital investments and 3) are outcome-oriented, serving to enhance public health protection. A major goal of the program 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 international standards in Zambia, Malawi, and Lesotho.

- Activity #8.1 – AWWA to conduct a needs assessment survey to identify specific utility management standards of greatest interest to water sector utilities in Zambia, Malawi, and Lesotho and recruit a cohort of gender-diverse training participants from 15+ utilities
- Activity #8.2 – Develop training materials and agenda by AWWA staff and subject matter experts (SMEs)
- Activity #8.3 – Conduct training with participants from Zambia, Malawi, and Lesotho water utilities

The following Performance Indicators will be applicable in Activity #8 (specifically #8.3):

PI#2 Number of trainings conducted about the value of using their national quality infrastructure.

PI#4 Number of international standards adopted or referenced by partner country.

PI#5 Countries have an enabling environment for a national quality infrastructure.

PI#9 Number of workshop/reserve trade mission participants.

PI#16 Number of measures implemented to promote gender equality.

Expected results (in Year 4):

- Water sector utilities interested in learning about and adopting utility management standards are identified and recruited in Zambia, Malawi, and Lesotho
- Content for workshops describing utility management standards aimed at target audiences in Zambia, Malawi, and Lesotho is developed and tailored, based on findings from needs assessment survey
- Training workshop achieves attendance within 10% of expectations (at least 15 utilities participating in the training with at least 2 staff attending from each utility)
- Copies of 14 AWWA Utility Management Standards are shared with each training participant

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

Private sector partner: ASTM International and American Petroleum Institute (API)

Partner countries for Year 4: West Africa (Côte d'Ivoire, Ghana, Nigeria, Senegal)

Description: The scope of this project aims to increase understanding and implementation of international petroleum standards and procedures, and to bolster harmonization of petroleum standards in the ECOWAS region. Together ASTM International and the American Petroleum Institute (API) will work with national standards bodies and technical experts in four West African countries (Côte d'Ivoire, Ghana, Nigeria, and Senegal) to assess petroleum standards and procedures capacity and understanding. Following initial assessments, ASTM and API will work with the four countries to identify regional priorities and develop trainings to review relevant international standards. Through these trainings and associated capacity building activities, ASTM and API will aid the West African nations in coordinating a regional standards committee through ECOWAS as well as the African Refiners and Distributors Association (ARDA) to harmonize regional petroleum standards and procedures.

In parallel to trainings to support regional and national understanding of targeted standards, ASTM and API will introduce locally appropriate standards and procedures to local technicians and vocational institutions through a series of workshops and course materials.

- Activity #5.3 - Maintain regular consulting meetings to raise public and private sector awareness and understanding of relevant international standards
- Activity #5.5 - Hold a two-day working group meeting for technical experts in West Africa.
- Activity #5.6 – Conduct regular web conferences with working groups.
- Activity #5.8 – Conduct a one-week study tour for African participants to be held at ASTM technical meetings in Florida and at API Headquarters in Washington D.C
- Activity #5.9 – Host an exhibit booth and hold 2-day focal point meetings in conjunction

with the Offshore Technology Conference in Houston, TX.

The following Performance Indicators will be applicable in Activity #5:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure

PI#3 Number of new international standards activities in a country participates

PI#4 Number of international standards adopted or referenced by partner country

PI#5 Countries have an enabling environment for NQI

PI#6 Number of private sector participants in regulatory development project activities

PI#7 Number of participants in national technical committees

PI#8 Number of US industry WTO TBT concerns with partner countries eliminated

PI#9 Number of workshops/ reserve trade mission participants

PI#13 Number of WTO TBT notifications submitted by partner countries

Expected results: The project seeks to help rekindle the dormant ECOWAS Technical Committee for Petroleum Standards and enhance West African understanding of international petroleum standards and procedures. These efforts aim to aid the adoption of various API and ASTM standards at the regional level, which will bolster the quality and safety of local petroleum products for ECOWAS nation companies and users.

Activity #6 Africa Concrete and Building Code Adoption Initiative

Private sector partner: American Concrete Institute (ACI)

Partner countries for Year 4: Kenya, Uganda and Tanzania

Description: The scope of this project aims at building awareness and confidence with key decision makers and influencers (including public agencies, private sector stakeholders, business and industry, academic and non-governmental stakeholders) in target countries on the adoption and implementation of modern building codes for construction materials, based on ACI's code already applied worldwide. This demand driven activity has three phases: In Phase 1, a multi-stakeholder dialogue on modern concrete building codes is launched by ACI to understand domestic views and needs; In Phase 2, ACI advances understanding among key stakeholders, namely professors, civil engineers, construction companies and government officials of modern reinforced concrete building standards embraced by ACI; In Phase 3, after buy-in has been secured, ACI advises how to develop and implement a Concrete Building Code customized to the community's need.

- Activity #6.1 – RESEARCH: Research and identify contacts in Kenya, Uganda, and Tanzania, as well as other USAID eligible countries in Africa, for relevant government department/ministries, engineering societies, university faculties, and key businesses in the concrete industry.
- Activity #6.2 – MEETINGS (Virtual and In-Person): Begin meetings with interested parties from government ministries, standards organizations, engineering associations, and educational institutions to introduce ACI, establish relationships and raise awareness and understanding about the benefits of using ACI codes/standards and ACI code adoption. Includes an Africa wide webinar to introduce ACI to all interested parties in Africa, followed up with a survey to identify the countries with the highest development potential.

- Activity #6.3 – ANALYSIS: Gather findings and input collected during outreach, working group meetings and webinar/survey. Analyze to determine the feasibility of proceeding to Phase 2 in consultation with various stakeholders and establish a timeframe for proceeding to Phase 3.
- Activity #6.4 – OUTCOMES-High: Sign agreements with countries to adopt ACI codes/ standards. (Phase 3)
- Activity #6.5 – OUTCOMES-Medium: Work with local ACI champions (key structural engineers, professors, and code development personnel in appropriate ministries) to create a system for basing local code requirements on ACI standards and resources.
- Activity #6.6 – OUTCOMES-Medium: Conduct detailed consulting work to customize a functional ACI code for countries who decide to join the ACI code community (Phase 3)
- Activity #6.7 – OUTCOMES-Low: Conduct regular web meetings and follow-up with working established contacts

The following Performance Indicators will be applicable in Activity #6:

PI#1 Countries have developed their National Quality Infrastructure

PI#2 Number of trainings conducted about the value of using their national quality infrastructure (#6.2)

PI#5 Countries have an enabling environment for NQI

PI#6 Number of private sector participants in regulatory development project activities

Expected results:

- Create a conducive environment for the acceptance, use, and adoption of ACI standards and related technical programs to achieve the benefits of using these standards.
- Formalize agreements with entities in Uganda, Kenya, Tanzania, and other USAID eligible African countries to become ACI business partners or sponsorship groups.
- Acceptance and use of ACI developed technical requirements by design professionals in USAID eligible African countries, supported by a collection of ACI guides, reports, and technical education programs.
- Improve domestic infrastructure quality, setting the foundations of a functioning and enforceable set of codes and standards for structural concrete and encourage the establishment of ACI Chapters, ACI Student Chapters in USAID eligible African countries.
- Enhance quality assurance through qualified personnel certification programs implemented by sponsor groups operating with agreements.
- Integrate ACI design criteria into college and university engineering curricula and technical and vocational program curricula.

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)

Private sector partner: International Association of Plumbing and Mechanical Officials (IAPMO)

Partner countries for Year 4: Indonesia and the Philippines

Activities in the Philippines will only occur pending confirmation from USAID that the SA2 can work in the Philippines.

Description: Through the *Increase the Flow* project, IAPMO will work with the SA2 on two growing economies: Indonesia and the Philippines (pending confirmation from USAID that the SA2 can work in the Philippines). This project builds off successful projects previously carried out by IAPMO in each country, which laid a critical foundation. For this new phase of work, IAPMO has worked with industry stakeholders to identify specific hurdles and to develop discrete solutions that will enable the industry to “increase the flow” of safe plumbing products in these markets with an eye to developing reliable supply chains and expanding WASH-related services. This tailored approach is designed to help the private sector through long-lasting changes that ease market access requirements, address non-tariff barriers, and encourage the adoption of international developed standards that are industry-developed, science-based and internationally recognized.

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

Pending confirmation from USAID that the SA2 can work in the Philippines:

- Activity #7.2 – Conduct review of National Building Code of the Philippines (NBCP), Philippine Green Building Code (PGBC) and current technical regulations related to water efficiency
- Activity #7.3 - Develop a Standards Action Plan identifying international product standards that will establish baseline and “reach” efficiency standards for plumbing products in the Philippines technical regulations
- Activity #7.4 – Conduct review of the Philippines legal requirements for the import and conformity assessment of plumbing products

The following Performance Indicators will be applicable in Activity #7:

PI#1 Countries have developed their National Quality Infrastructure for WASH (#7.1 and 7.2)

PI#2 Trainings conducted about the value of using their National Quality Infrastructure (#7.1)

PI#3 Number of new international standards activities in which country participates. (#7.1)

PI#4 Number of international standards adopted or referenced by partner country in their law (#7.1 and 7.3)

PI#5 Countries have an enabling environment for a National Quality Infrastructure (#7.1 and 7.3)

PI#6 Number of private sector participants in regulatory development project activities. (#7.2 and 7.3)

PI#7 Number of participants in national technical committees (#7.1)

PI#14 Number of countries with transparent national quality infrastructure practices (#7.4)

Expected results:

- Work with the National Standardisation Agency of Indonesia (BSN) to prepare a draft Indonesian national standard (SNI) related to water faucets and convene a Technical Committee meeting (Indonesia)

- Developed Standards Action Plan (Philippines)
- Identified challenges in current conformity assessment scheme impacting water efficiency (e.g. testing waivers for importers, post-sampling adjustments)
- Developed Conformity Assessment Action Plan (Philippines)

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

Private sector partner: American Water Works Association (AWWA)

Partner countries for Year 4: India

Description: AWWA will utilize its series of 14 Utility Management Standards that focus on water utility management practices. The trainings will be tailored to stated participant needs/goals, with guidance provided for optimization of various aspects of management practices and operations. These standards 1) are applicable to utilities of all sizes and types, including potable water, wastewater and reclaimed water utilities, 2) can be implemented without major capital investments and 3) are outcome-oriented, serving to enhance public health protection. AWWA intends to utilize existing WASH utility networks and subject matter experts built by its India office to strengthen WASH management practices in India. A major goal of the program 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 international standards in India.

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

The following Performance Indicators will be applicable in Activity #8:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure.

PI#4 Number of international standards adopted or referenced by partner country.

PI#5 Countries have an enabling environment for a national quality infrastructure.

PI#9 Number of workshop/reserve trade mission participants.

PI#16 Number of measures implemented to promote gender equality.

Expected results (in Year 4):

- Water sector utilities interested in learning about and adopting utility management standards are identified and recruited in India
- Content for workshops describing utility management standards aimed at target audiences in India is developed and tailored, based on findings from needs assessment survey
- Training workshop achieves attendance within 10% of expectations (at least 15 utilities participating in the training with at least 2 staff attending from each utility)
- Copies of 14 AWWA Utility Management Standards are shared with each training participant

LATIN AMERICA

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

Activity #9 – Community Water Systems – Standards for safety and risk management (also appears in Middle East)

Private sector partner: NSF International

Partner countries for Year 4: Brazil

Description: Through its Community Water Systems project, NSF International is working with the SA2 in Brazil on sensitizing and training key stakeholders on the importance of adoption and application of NSF/ANSI drinking water standards, which nearly all U.S. states require (49 out of 50 states). These standards work to improve public health by establishing minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water from products, components and materials used in drinking water systems or chemicals used to treat drinking water. NSF International is aiming to engage the in-country regulator and other governmental stakeholders, manufacturers, water providers and user groups to sensitize and train on the value of how established ANSI/CAN standards seek to ensure safe wetted contact and performance for those products used in community water systems. The goal is to create a driver for manufacturer compliance to the standards via strengthening of regulation and as a procurement requirement for water providers. Product certification will not only advance public health regarding drinking water safety in Brazil, but certification will greatly improve marketability for the manufacturers globally, with an emphasis on North America.

- Activity #9.3 – Hold trainings to address barriers to trade and awareness of other issues; building on the initial training for NSF/ANSI/CAN Standard 61 held during Q2 2022, and upcoming training for NSF/ANSI/CAN Standard 60 planned for Q3/Q4 2022.

The following Performance Indicators will be applicable in Activity #9:

PI#3 Number of new international standards activities in which country participates.

PI#4 Number of international standards adopted or referenced by partner country.

PI#5 Countries have an enabling environment for a national quality infrastructure.

PI#6 Number of private sector participants in regulatory development project activities.

PI#7 Number of participants in national technical committees.

PI#8 Number of U.S. industry WTO TBT concerns with partner countries eliminated.

PI#9 Number of workshop/reserve trade mission participants

Expected results (in Year 4):

- Continue to establish working relationships with regulatory and government WASH stakeholders in Brazil, who have been sensitized to the value and importance of NSF's drinking water standards
- Continue formation of a baseline list of Brazilian regulators, operators and manufacturers to be trained in program year 4

MIDDLE EAST NORTH AFRICA

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

Activity #9 – Community Water Systems – Standards for safety and risk management (also appears in Latin America)

Private sector partner: NSF International

Partner countries for Year 4: Morocco

Description: Through its Community Water Systems project, NSF International is working with the SA2 in Morocco on sensitizing and training key stakeholders on the importance of adoption and application of NSF/ANSI drinking water standards, which nearly all U.S. states require (49/50). These standards work to improve public health by establishing minimum health effects and requirements for chemical contaminants and impurities that are directly imparted to drinking water from products, components and materials used in drinking water systems or chemicals used to treat drinking water. NSF International is aiming to engage the in-country regulator and other governmental stakeholders, manufacturers, water providers and user groups to sensitize and train on the value of how established ANSI/CAN standards seek to ensure safe wetted contact and performance for those products used in community water systems. The goal is to create a driver for manufacturer compliance to the standards via strengthening of regulation and as a procurement requirement for water providers. Product certification will not only advance public health regarding drinking water safety in Morocco, but certification will greatly improve marketability for the manufacturers globally, with an emphasis on North Africa.

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

The following Performance Indicators will be applicable in Activity #9:

PI#3 Number of new international standards activities in which country participates.

PI#4 Number of international standards adopted or referenced by partner country.

PI#5 Countries have an enabling environment for a national quality infrastructure.

PI#6 Number of private sector participants in regulatory development project activities.

PI#7 Number of participants in national technical committees.

PI#8 Number of U.S. industry WTO TBT concerns with partner countries eliminated.

PI#9 Number of workshop/reserve trade mission participants

Expected results (in Year 4):

- Developed action plan formed by findings of the needs assessment, with input from key stakeholders, which includes areas for improvement, how to handle existing gaps, and ways forward in year 4
- Established working relationships with regulatory and government WASH stakeholders in Morocco, who have been sensitized to the value and importance of NSF's drinking water standards
- Formation of a baseline list of Morocco regulators, operators and manufacturers to be trained in program year 4

GENERAL/PROGRAM MANAGEMENT

In addition to the above work plan activities, ANSI will conduct the following tasks to support administration of the SA2 in Year 4:

- 1) Program new SA2 funds – In September 2022 the SA2 completed a modification that added funds and extended the timeline of the project. In order to effectively implement these funds, in the beginning of Year 4 ANSI will undertake outreach to key private sector partners to develop concept notes for new activities, and will work with USAID to socialize these proposed activities with relevant USAID Missions. In particular, ANSI will prioritize the following subjects and stakeholders for outreach:
 - Automobiles – including electric vehicles
 - Digital infrastructure – including support for USAID Digital Inclusion priorities such as connectivity;
 - Energy – including support for addressing climate change and promoting a gender-equitable workforce;
 - Sustainable cities – promoting sustainable city planning in communities;
 - Agriculture – including food labeling and food analysis; and
 - Water and sanitation – expand successful SA2 activities to countries that have been Congressionally notified with the new funds.

ANSI will work with private sector partners to develop concept notes according to the template developed in consultation with USAID during Year 1 of the SA2, and will secure USAID approval for each activity before adding it to the work plan.

- 2) Website development – ANSI, will monitor and update the specific SA2 website that includes information on projects, relevant SA2 resources, and points of contact. ANSI will work with USAID to ensure all Branding and Marking requirements are upheld in the revised website. The website has been launched in Year 3.
- 3) Maintenance of strategic partnerships - According to the strategic objectives set for the SA2, the SA2 will continue to explore collaboration opportunities with entities that provide technical assistance on NQI related matters, and if appropriate, will develop strategic partnerships. This work will allow the SA2 to maximize the impact of its technical assistance by leveraging other organizations' resources. It will also ensure that the technical assistance approach of other organizations is balanced in terms of the value that they give to a system built around voluntary consensus standards, and the adoption of a multiple path approach. USAID/CEMD's support to connect and follow-up with these organizations will be particularly helpful as such organizations may not have channels for engaging private sector actors or initiatives like the Standards Alliance. In particular, these opportunities may include:

- African Union (AfCFTA Secretariat): Partnerships to implement the TBT Chapter of the African Continental Free Trade Agreement (AfCFTA)
 - African Organisation for Standardisation (ARSO): Collaboration on expanding capacity building and workshops on renewable energy
 - Asia-Pacific Economic Cooperation (APEC): Collaboration with the Industry Dialogues (e.g., Automotive Dialogue, Chemical Dialogue, Life Sciences Innovation Forum)
 - Association of Southeast Asian Nations (ASEAN): Collaboration with the consultative Committee on Standards and Quality (ACCSQ)
- 4) Coordination with USAID Bureaus and Missions – to implement projects in partner countries, ANSI and private sector partners reach out to relevant USAID Missions to present on the project, brief them on opportunities, and request concurrence, if needed. In Year 3, ANSI reached out to various Missions in all SA2 regions and navigated the patchwork of disparate Mission requirements. ANSI values Mission involvement and support and will continue to conduct outreach with them before starting implementation and during design, as a best practice to align and streamline project goals with USAID's broader work and ensure Mission Concurrence.

2.3 LIST OF ACTIVITIES FOR YEAR 4 (JULY 12, 2021 – JULY 11, 2022) – COVID-19 RELATED

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

Private sector partner: Ethical Apparel Africa (EAA) with support from Maagrace Garment Institute Limited

- In August 2020, ANSI and EAA finalized a subaward agreement for EAA to carry out the referenced activity as a private sector partner under the SA2.

Partner countries for Year 4: Ghana

Description: The primary scope of this activity is to support the government of Ghana's efforts to establish production for personal protective equipment (PPE), primarily, surgical grade PPE. This project aims to inform government officials and local producers on relevant international processes and procedures to meet US market requirements for PPE. Additionally, it will support the use of international standards for the production of high-quality PPE to position local producers to transition manufacturing to meet the Ghanaian and broader West African need for high quality PPE.

Ethical Apparel Africa (EAA), in coordination with Maagrace Garment Industries Limited, have established a plan to produce surgical grade Level 2 masks and then other PPE, such as disposable

gowns. This project will add technical expertise needed to ensure government agencies and local production processes and PPE is fully accredited, tested and certified to ASTM standards and for sale domestically and internationally.

In addition, this project aims to support government understanding of international best practices for the production of PPE to establish Ghana as a hub for PPE production by working with government agencies such as the Ghana FDA and the Ghana Standards Authority to institutionalize international best practice for PPE production.

This project continues to be significantly delayed resulting from the recent Covid 19 lockdowns in China, specifically, Shanghai. EEA failed its first round of testing and needed a new batch of fabrics to send sample masks for testing in the USA. The 2nd batch of sample masks are now in the USA undergoing testing to meet ASTM Level 2 standard. Once they pass, EEA will be able to move things forward with the standards authority and to begin selling. EEA is working to develop the Quality Management System to test for PPE conformity in Ghana. This will require registration through the Ghana Standards Agency (GSA), and once approved, the project can be declared a success.

- Activity #11.5 – Specialist training programs for Ghana Ministry of Health, Ghana Ministry of Trade and Industry, Ghana FDA, and GSA on quality requirements and procuring PPE (August- October 2022)
- Activity #11.6 – Train the sales & operating team at EAA and Maagrace to follow SOP's and ensure continued standard adherence (October 2022)
- Activity #11.7 – Ghana FDA standards & packaging requirements established and trained (October 2022)
- Activity #11.8 – Establish relationships and sales pipeline for product across ECOWAS and USA (October 2022)
- Activity #11.9 – Procure a mask making machine and sample correct fabrics and trims to achieve mask and gown testing standards (August – September 2022 – Machinery was installed during SA2 Year 2)

Given the delays in starting implementation the applicable performance indicators for this activity have not been defined.

Expected results:

The table below contains a list of expected outcomes with qualitative and quantitative targets.

Outcome/Output	Targets
Outcome: Strengthen capacity of Government Officials/Agencies on PPE standards	Ministry of Health, Ministry of Trade and Industry Ghana FDA and Ghana Standards Authority receive training for at least 20 people in Year 4
Outcome: Improve Private Sector knowledge on PPE standards and how to leverage them for production diversification	At least 2 walk through sessions in conjunction with Maagrace and EAA for other factories

Outcome: prepare EAA for product certification / accreditation / testing standards under ASTM Level 2	Identification of testing and labelling standards Submit samples to accredited lab with associated paperwork on time
Outcome: Support the creation of access to clean room environment that meets international standards (ISO 7 standards)	Any external process accreditation needed is identified and achieved alongside the ISO7 standard
Output: Documented training and SOP's showing knowledge and skill development of the local factory team to be able to sustainably manage this production unit into the future	Maagrace and EAA receive training for at least 50 people by October 2022

GLOBAL

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

Private sector partner: Advanced Medical Technology Association (AdvaMed)

Description: The COVID-19 Medical Device Regulatory Convergence Project (MDRC), implemented by AdvaMed, was launched to support the implementation of internationally harmonized standards and good regulatory practices GRP in the medical technology sector. MDRC provides resources and expertise in support of international, regional, sub-regional and national governmental initiatives in Latin America, Africa, and Southeast Asia to implement medical device sector-specific regulatory convergence. The timely nature of this project contributes to its unique capacity to support ongoing efforts to combat and support recovery from COVID-19.

Partner countries for Year 4: Brazil, Colombia, Mexico, Peru, Kenya, South Africa, Ghana, Vietnam, and Indonesia. These countries were chosen in part due to their importance within their respective regions and sub-regions, with the aim of facilitating additional project benefits in surrounding regions.

One major implementation challenge in Project Year 3 (July 2021 – June 2022) was workstream execution delays related to slower engagement by some project country governments. In Indonesia and Vietnam, MDRC experienced long periods between government stakeholder responses to project outreach, despite the fact that both countries' Tier Two government stakeholders remain interested in partnering with the project. If delays continue in Vietnam, the MDRC may reevaluate its allocation of resources to the project country during Q3 2022, with the support of USAID.

In Ghana, MDRC conducted outreach in July 2021 when Kenya and South Africa had secured Mission concurrence. However, even after indicating interest in partnering with MDRC, the Ministry has not responded to follow-up by MDRC. MDRC has been working with local and regional stakeholders to continue outreach with Ghana's Tier One and Two agencies. This

includes the U.S. Trade Representative, Department of Commerce, and Department of State. In Project Year 4, with the potential creation of a Nairobi-based MDRC Liaison, MDRC will explore re-examining its level of engagement with Ghana to maximize effectiveness of capacity building resources.

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 may be a barrier to MDRC's ability to fully realize its project objectives.

GLOBAL

Activities:

- 12.1 – The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition) will lead in implementing and managing a dedicated COVID-19 Medical Device workstream at the global level on behalf of the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) working in conjunction with the IMDRF.
- 12.2 - Annual GMTA/GDA Side Meeting of the International Center for Emergency Regulatory Response and “international benchmarks” report (2023)
- 12.3 – The Coalition will promote, ensure, measure, and report the engagement of women throughout the implementation of the project in all geographies.

Expected Results:

The Coalition will continue advancing MDRC objectives in its leadership for the implementation of the International Center for Emergency Regulatory Response (ICERR) in the form of a dedicated COVID-19 Medical Device workstream of the GMTA/GDA. This workstream was approved in principle in 2020-2021 and formally constituted by the GMTA Regulatory Committee in September 2021. The Coalition expects to support GMTA in the: Development of COVID-19 recommendations to IMDRF, WHO, G/AHWP regarding appropriate international benchmarks; Organization of a MDRC-related training to address pandemic/emergency elements; and Inclusion of links to the MDRC project website and any related resources on the GMTA website. MDRC aims to advance those items with GMTA as part of an advisory group with members from the Coalition, AdvaMed, MedTech Europe, Mecomed, private companies, and a standard developing organization (SDO). The Coalition will generate an Annual Status Report on the Engagement of Women (Q3 2022).

AFRICA

Partner countries: Ghana, Kenya and South Africa

Activities:

- 12.4 – Tier One GRP Implementation (foundational): Gap Analysis and Stakeholder Assessment (Q3 2022 – Q2 2023)
- 12.5 – Tier One and Two Local Meetings/Trainings (Q3 2022 – Q2 2023)
- 12.6 – Tier One and Two Regional Meetings/Trainings (Q3 2022 – Q2 2023)
- 12.7 – Help lead development and execution of MDRC-related workstreams through the GMTA Africa Working group, constituting an African Coalition for Regulatory Convergence in the Medical Technology Sector (Q3 2022 – Q2 2023)
- 12.8 – Hire a dedicated MDRC Liaison facilitate and coordinate the implementation of MEL Plan objectives in Kenya and region (pending Government of Kenya and USAID approval). (TBD)

Expected results:

MDRC will socialize the Tier One Working Document with relevant stakeholders, incorporating input and feedback as received. A final version of the report will be released at the conclusion of the project. In partnership with local and regional medical device industry partners, host Tier One and Two meetings/trainings at the local and regional levels. The ability of MDRC to host these events and their timelines are dependent on the approval of MDRC workstreams by partner country governments.

These events include:

- Tier One/Two local meetings/trainings, South Africa (Virtual) (Q3 2022 – Q2 2023)
- Tier One Regional Forum, Kenya (In-Person or Virtual) (Q3 2022)
- Tier One/Two local meeting/training, Kenya (In-Person or Virtual) (Q4 2022 – Q2 2023)
- Tier One/Two local meeting/training, Ghana (In-Person or Virtual) (Q4 2022) (TBD on approval of workstream by Government of Ghana)
- Tier Two Regional Forum, South Africa (In-Person or Virtual) (Q1 2023)
- Tier Two Regional Forum, Kenya In-Person or Virtual (Q1 2023)

Through the execution of these Tier One and Two meetings/trainings, MDRC aims to increase the number of:

- Key agencies and authorities participating in these consultations
- Project Countries agreeing to implement GRP
- Project Countries agreeing to implement WTO TBT consistent Standards and Conformity policies

MDRC will work with the GMTA Africa Working Group to develop and lead the implementation of workstreams related to regulatory convergence and other MDRC objectives. This working group will act as an African coalition for regulatory convergence in the medical technology sector, coordinating industry efforts to maximize the effectiveness of MDRC technical assistance in the region.

Fast-track MEL plan fulfillment through the engagement of a dedicated MDRC Liaison to Kenya. The Liaison will (a) conduct a formal situational analysis of Tier Two areas for improvement among relevant Kenyan stakeholders, and (b) facilitate and coordinate the implementation of MEL Plan objectives in Kenya and region. The creation of the Liaison position is dependent on the approval of the Government of Kenya and USAID.

INDO-PACIFIC

Partner countries: Indonesia and Vietnam

Activities:

- 12.9 – Tier One GRP Implementation (foundational): Gap Analysis and Stakeholder Assessment (Q3 2022 – Q2 2023)
- 12.10 – Tier Two Local Meetings/Trainings (Q3 2022 – Q2 2023)
- 12.11 – Tier Two Regional Meetings/Trainings (Q3 2022 – Q2 2023)

Expected results:

MDRC will socialize the Tier One Working Document with relevant stakeholders, incorporating input and feedback as received. A final version of the report will be released at the conclusion of the project.

Host Tier One and Two meetings/trainings at the local and regional levels. This includes:

- Tier Two Regional Meeting/Training, Indonesia (In-Person or Virtual) (Q3/Q4 2022)
- Tier Two Local Meetings/Trainings, Indonesia (In-Person or Virtual) (Q3/Q4 2022)
- Tier Two Regional Meeting/Training, Vietnam (In-Person or Virtual) (Q4 2022/Q1 2023) (TBD/tentative program based on approval of workstream by Ministry of Health)
- Tier Two Local Meetings/Trainings, Vietnam (In-Person or Virtual) (Q3/Q4 2022) (TBD/tentative program based on approval of workstream by Ministry of Health)

Through the execution of these Tier One and Two meetings/trainings, MDRC aims to increase the number of:

- Key agencies and authorities participating in these consultations
- Project Countries agreeing to implement GRP
- Project Countries agreeing to implement WTO TBT consistent Standards and Conformity policies

LATIN AMERICA

Partner Countries: Brazil, Colombia, Mexico, Peru

Activities:

- 12.12 – The Coalition will lead regional MDRC project efforts, convene stakeholders for meetings/trainings, and provide capacity-building resources. (Q3 2022 – Q2 2023)
- 12.13 – Engagement with key partners, including IDB, WTO, and PAHO. (Q3 2022 – Q2 2023)
- 12.14 – Leverage MDRC Liaison to facilitate and coordinate the implementation of MEL Plan objectives in Colombia (Q3 2022 – Q2 2023)

- 12.15 – Updated Tier One and Two Gap Analysis Reports (Q3 2022 – Q2 2023)
- 12.16 – Tier One and Two Implementation Meetings and Workshops with Project Countries and regional stakeholders. (Q3 2021 – Q2 2022)

Expected results:

The Coalition's website advances MDRC objectives by serving as a centralized resource for parties, including regulatory and customs authorities, to validate non-proprietary information from industry related to foreign approvals, licenses, regulations, and applicable standards. It provides a compilation of available information from the FDA or other relevant USG agencies of the newest medical devices released by the industry to fight the COVID-19 pandemic.

Engagement with IDB/ABD:

- Increased alignment of the trade, GRP, and health work within the IDB
- Engagement with the Ibero-American Regulatory Improvement Network

Engagement with WTO/TBT/GRP Geneva, Switzerland:

- Further engagement with relevant committees to increase understanding of TBTs for the medical device sector and the role of GRP has in addressing them.

Continue to fast-track MEL plan fulfillment through the engagement of a dedicated MDRC Liaison to Colombia. The Liaison will coordinate and work with relevant Colombian government stakeholders to implement regulatory convergence and GRPs, even in a virtual setting.

MDRC will socialize the Tier One Working Document with relevant stakeholders, incorporating input and feedback as received. A final version of the report will be released at the conclusion of the project.

Execution of Tier One and Two meetings/trainings with regional and local stakeholders. MDRC aims to increase the number of:

- Key agencies and authorities participating in these consultations
- Project Countries agreeing to implement GRP
- Project Countries agreeing to implement WTO TBT consistent Standards and Conformity policies
- Project Countries agreeing to implement emergency use authorizations based on international benchmarks

The following Performance Indicators will be applicable in Activity #12:

PI#2 Number of trainings conducted about the value of using their national quality infrastructure

PI#3 Number of new international standards activities in a country participates

PI#4 Number of international standards adopted or referenced by partner country

PI#5 Countries have an enabling environment for NQI

PI#6 Number of private sector participants in regulatory development project activities

PI#7 Number of participants in national technical committees

PI#8 Number of US industry WTO TBT concerns with partner countries eliminated

PI#9 Number of workshops/ reserve trade mission participants

PI#10 Number of host-country COVID-19 preparedness and/or response plans in various phases (formally proposed, adopted, or implemented) supported with USG assistance

PI#11 Number of trade facilitating procedures implemented during CV-19 with USG assistance.

PI#12 Number of laws or regulations proposed, adopted, or implemented to facilitate trade during CV-19 with USG assistance

PI#13 Number of WTO TBT notifications submitted by partner countries

PI#16 Number of measures implemented to promote gender equality

Table I: Year 4 Activity Summary

GLOBAL			
DEVELOPMENT OBJECTIVE	ACTIVITIES	EXPECTED RESULTS	STATUS
Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner	<p>12.1 The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition) will lead in implementing and managing a dedicated COVID-19 Medical Device work stream at the global level on behalf of the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) working in conjunction with the IMDRF</p> <p>12.2 The Coalition will promote, ensure, annual GMTA/GDA Side Meeting of the International Center for Emergency Regulatory Response and "international benchmarks" report</p> <p>12.3 The Coalition will promote, ensure, measure, and report the engagement of women throughout the implementation of the project in all geographies</p>	<p>1. The Coalition continues advancing MDRC objectives in its leadership virtually establishing and leading the implementation of the International Center for Emergency Regulatory Response (ICERR) in the form of a dedicated COVID-19 Medical Device work stream of the GMTA/GDA.</p> <p>2. The Coalition generates an Annual Status Report on the Engagement of Women.</p>	In implementation.
Countries have developed their national quality infrastructure	13.1 (New) Support for critical minerals standardization coordination	1. Expand the U.S. stakeholder group that participates in the ISO SAG, thereby facilitating more robust U.S. input into the international results, while also facilitating U.S. leadership of SAG recommendations and future international standardization around critical minerals.	In development.
AFRICA			
DEVELOPMENT OBJECTIVE	ACTIVITIES	EXPECTED RESULTS	STATUS
Countries have developed their national quality infrastructure	1.1 Continue a regional workshop in coordination with ECOWAS and ECREEE to train regional experts and build momentum for standards adoption, and pursue webinars on Bioethanol with ARSO	<p>1. Adoption of international ethanol standard for household energy use</p> <p>2. Adoption/Adaption of a regional standard for renewable transportation fuels</p>	Regional workshop completed. Standards adoption in 2 ECOWAS countries is still in the works. 3 Bioethanol webinars are pending implementation with ARSO in Q3 & Q4.

2.1 Finalize the cosmetics webinars series with ARSO and PCPC	1. Enhance African continental understanding of specific international standards and the standards development process	In implementation
3.2 Conduct in-person or virtual interviews with Ministries, regulators, National Standards Bodies, utilities, private sector partners and civil society organizations	1. Continue development of 3 comprehensive, country-level reports (one for each country), based on the deskwork and interviews, which evaluates the national-level laws, regulations and policies governing the development, adoption and use of WASH related standards	Debut of virtual interviews Q3 2022
3.3 Incorporate findings from deskwork and interviews into comprehensive country-level reports	2. Development of recommendations for in-country partners for addressing shortcomings discovered in country-level reports in each country 3. Two virtual sessions per country with critical stakeholder to discuss results and recommendations based on the comprehensive country level diagnostic report 4. Development and dissemination of one trend report examining trends on how the law creates a commitment to increasing access to drinking water and sanitation, how the law supports the adoption and application of WASH standards, and how the law creates an enabling environment for NQI and reduces barriers to trade in international WASH products 5. Greater transparency of the laws governing the adoption and use of WASH standards 6. Greater transparency of the institutions responsible for developing WASH standards or whose activities influence the development of the WASH standards	
8.1 – AWWA to conduct a needs assessment survey to identify specific utility management standards of greatest interest to water sector utilities in Zambia, Malawi, and Lesotho and recruit a cohort of gender-diverse training participants from 15+ utilities	1. Water sector utilities interested in learning about and adopting utility management standards are identified and recruited in Zambia, Malawi, and Lesotho 2. Content for workshops describing utility management standards aimed at target audiences in	In implementation. Africa workshops to begin in Year 4.

	<p>8.2 – Develop training materials and agenda by AWWA staff and subject matter experts (SMEs)</p> <p>8.3 – Conduct training with participants from Zambia, Malawi, and Lesotho water utilities</p>	<p>Zambia, Malawi, and Lesotho is developed and tailored, based on findings from needs assessment survey</p> <p>3. Training workshop achieves attendance within 10% of expectations (at least 15 utilities participating in the training with at least 2 staff attending from each utility)</p> <p>4. Copies of 14 AWWA Utility Management Standards are shared with each training participant</p>	
Private sector actively participates in countries' national quality infrastructure	<p>Activity #5.3 - Maintain regular consulting meetings to raise public and private sector awareness and understanding of relevant international standards</p> <p>Activity #5.5 - Hold a two-day working group meeting for technical experts in West Africa.</p> <p>Activity #5.6 – Conduct regular web conferences with working groups.</p> <p>Activity #5.8 – Conduct a one-week study tour for African participants to be held at ASTM technical meetings in Florida and at API Headquarters in Washington D.C</p> <p>Activity #5.9 – Host an exhibit booth and hold 2-day focal point meetings in conjunction with the Offshore Technology Conference in Houston, TX</p>	<p>1. Reactivate the ECOWAS Technical Committee for Petroleum Standards</p> <p>2. Enhance West African understanding of international petroleum standards and procedures</p> <p>3. Increase regional standards harmonization</p>	<p>In implementation. Activity 5.5 has been completed. 1 webinar conference with working groups is planned for in Q3 and the study tour will take place in Q4.</p>
	<p>6.1 Build awareness on ACI codes and promote the use of ACI's 318 Building Code requirements for Structural Concrete and Commentary.</p>	<p>1. Build relationships, provide identified partners countries with a functioning and enforceable set of codes and standards for structural concrete and encourage the establishment of ACI Chapters, ACI Student Chapters in target countries.</p>	<p>Subaward finalized in June 2021 and pre-implementation with outreach meetings began in Q1 2022. An Africa wide awareness-building workshop is being planned for Q3 to gauge the interest of new countries interest in working with ACI on standards adoption, outside of Uganda and Kenya who are currently implementing Euro standards and to raise awareness of ACI's offering.</p>
Countries have COVID-19 plans that leverage their NQI in	<p>11.2 – Ensure international compliance standards are met in line with apparel</p>	<p>1. Ministry of Health, Ministry of Trade and Industry Ghana FDA and Ghana Standards Authority</p>	<p>In implementation.</p>

a trade-facilitating manner	<p>production to ensure safe place to work</p> <p>11.3 – Establish personnel structure with clear career pathways for excelling workers</p> <p>11.5 – Specialist training programs for Ghana Ministry of Health, Ghana Ministry of Trade and Industry, Ghana FDA and GSA on quality requirements and procuring PPE</p>	<p>receive training for at least 20 people</p> <p>2. Local Private sector receive training for at least 50 people to understand and utilize international best practice</p>	
	<p>12.4 – Tier One GRP Implementation (foundational): Gap Analysis and Stakeholder Assessment</p> <p>12.5 – Tier One and Two Local Meetings/Trainings</p> <p>12.6 – Tier One and Two Regional Meetings/Trainings</p> <p>12.7 – Help lead development and execution of MDRC-related workstreams through the GMTA Africa Working group, constituting an African Coalition for Regulatory Convergence in the Medical Technology Sector</p> <p>12.8 – Hire a dedicated MDRC Liaison facilitate and coordinate the implementation of MEL Plan objectives in Kenya and region (pending Government of Kenya and USAID approval).</p>	<p>1. Publication of a unified Tier One report that includes the analyses and literature reviews from all project countries.</p> <p>2. Publication of maps of stakeholders in the Project Countries responsible for and involved in the implementation (1) the implementation of GRP, or (2) the implementation of medical device regulations, standards, and requirements, including medical device regulatory authorities and other governmental and non-governmental entities, both national and regional.</p> <p>3. Tier One and Two meetings/trainings conducted at the local and regional levels. These events include:</p> <p>4. Tier One Regional Forum, Kenya (Virtual)</p> <p>5. Tier One/Two local meeting/training, Kenya (Virtual)</p> <p>6. Tier One/Two local meeting/training, Ghana (Virtual)</p> <p>7. Tier Two Regional Forum, South Africa (In-Person or Virtual)</p> <p>8. Tier One/Two local meeting/training, South Africa (In-Person or Virtual)</p> <p>9. Increased: key agencies and authorities participating in these consultations, project Countries agreeing to implement GRP, and project Countries agreeing to implement WTO TBT commitments</p>	In implementation.

INDO-PACIFIC

DEVELOPMENT OBJECTIVE	ACTIVITIES	EXPECTED RESULTS	STATUS
Countries have developed their national quality infrastructure	<p>7.1 – Initiate development of new Indonesian national standard related to water faucets, based on existing international standards.</p> <p><i>(pending confirmation from USAID that the SA2 can work in the Philippines)</i></p> <p>7.2 Conduct review of National Building Code of the Philippines (NBCP), Philippine Green Building Code (PGBC) and current technical regulations related to water efficiency</p> <p>7.3 – Develop a Standard Action Plan identifying international product standards that will establish baseline and "reach" efficiency standards for plumbing products in the Philippines technical regulations</p> <p>7.4- Conduct review of the Philippines legal requirements for the import and conformity assessment of plumbing products</p>	<p>1. Work with the National Standardisation Agency of Indonesia (BSN) to prepare a draft Indonesian national standard (SNI) related to water faucets and convene a Technical Committee meeting (Indonesia)</p> <p>2. Developed Standards Action Plan (Philippines)</p> <p>3. Identified challenges in current conformity assessment scheme impacting water efficiency (e.g. testing waivers for importers, post-sampling adjustments)</p> <p>4. Developed Conformity Assessment Action Plan (Philippines)</p>	Indonesia activities are underway. Standard development and publication expected to be complete Year 4.
	8.3 – Conduct training with participants from 15+ Indian water utilities in Mumbai and Hyderabad	<p>3. Training workshop achieves attendance within 10% of expectations (at least 15 utilities participating in the training with at least 2 staff attending from each utility)</p> <p>4. Copies of I4 AWWA Utility Management Standards are shared with each training participant</p>	India workshops are underway and expected to be complete in Year 4.
Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner	<p>12.9 – Tier One GRP Implementation (foundational): Gap Analysis and Stakeholder Assessment (Q3 2022 – Q2 2023)</p> <p>12.10 – Tier Two Local Meetings/Trainings (Q3 2022 – Q2 2023)</p> <p>12.11 – Tier Two Regional Meetings/Trainings</p>	<p>1. Publication of a unified Tier One report that includes the analyses and literature reviews from all project countries.</p> <p>2. Publication of maps of stakeholders in the Project Countries responsible for and involved in the implementation of (1) GRP, or (2) medical device regulations, standards, and requirements.</p> <p>3. Host Tier One and Two meetings/trainings at the local and regional levels. This includes:</p> <ul style="list-style-type: none"> COVID-19 Medical Device regulatory 	In implementation

	<ul style="list-style-type: none"> review conference on the sidelines of the IMDRF (Virtual) ○ Tentative Tier Two Regional Meeting/Training, Vietnam (Virtual) ○ Tentative Tier Two Local Meeting/Training, Vietnam (Virtual) <p>4. Increased: key agencies and authorities participating in these consultations, project Countries agreeing to implement GRP, and project Countries agreeing to implement WTO TBT commitments</p>
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LATIN AMERICA			
DEVELOPMENT OBJECTIVE	ACTIVITIES	EXPECTED RESULTS	STATUS
Countries have developed their national quality infrastructure	<p>9.2 – Conduct regulatory and governmental outreach and relationship building and strengthening to facilitate discussions on the benefits of NSF/ANSI/CAN drinking water standards</p> <p>9.3 – Convene stakeholders to increase awareness of the value of the program, including addressing barriers to trade</p>	<p>1. Developed action plan formed by findings of the needs assessment, with input from key stakeholders, which includes areas for improvement, how to handle existing gaps, and ways forward in year 4</p> <p>2. Established working relationships with regulatory and government WASH stakeholders in Brazil, who have been sensitized to the value and importance of NSF's drinking water standards</p> <p>3. Formation of a baseline list of Brazilian regulators, operators and manufacturers to be trained in program year 3 and 4.</p>	In implementation. Workshops are underway in Brazil.
Countries have COVID-19 plans that leverage their NQI in a trade-facilitating manner	<p>12.12 – The Coalition will lead regional MDRC project efforts, convene stakeholders for meetings/trainings, and provide capacity-building resources.</p> <p>12.13 – Engagement with key partners, including IDB, WTO, and PAHO.</p> <p>12.14 – Leverage MDRC Liaison to facilitate and coordinate the implementation of MEL Plan objectives in Colombia</p>	<p>1. Engagement with IDB/ABD:</p> <p>2. Increased alignment of the trade, GRP, and health work within the IDB</p> <p>3. Engagement with the Ibero-American Regulatory Improvement Network</p> <p>4. Engagement with WTO/TBT/GRP Geneva, Switzerland:</p> <p>5. Further engagement with relevant committees to increase understanding of</p>	In implementation

12.15 – Updated Tier One and Two Gap Analysis Reports	TBTs for the medical device sector and the role of GRP has in addressing them.
12.16 – Tier One and Two Implementation Meetings and Workshops with Project Countries and regional stakeholders.	<p>7. Fast-track MEL plan fulfillment through the engagement of a dedicated MDRC Liaison to Colombia.</p> <p>8. Publication of a unified Tier One report that includes the analyses and literature reviews from all project countries.</p> <p>9. Execution of Tier One and Two meetings/trainings with regional and local stakeholders.</p> <p>10. Increased: key agencies and authorities participating in these consultations, project Countries agreeing to implement GRP, project Countries agreeing to implement WTO TBT commitments</p>

MIDDLE EAST NORTH AFRICA

DEVELOPMENT OBJECTIVE	ACTIVITIES	EXPECTED RESULTS	STATUS
Countries have developed their national quality infrastructure	<p>9.1 – Conduct a needs assessment to determine the guidelines and processes drinking water providers in Peru are currently using</p> <p>9.2 – Conduct regulatory and governmental outreach and relationship building and strengthening to facilitate discussions on the benefits of NSF/ANSI/CAN drinking water standards</p> <p>9.3 – Convene stakeholders to increase awareness of the value of the program, including addressing barriers to trade</p>	<p>1. Developed action plan formed by findings of the needs assessment, with input from key stakeholders, which includes areas for improvement, how to handle existing gaps, and ways forward in year 3 and year 4</p> <p>2. Established working relationships with regulatory and government WASH stakeholders in Morocco, who have been sensitized to the value and importance of NSF's drinking water standards</p> <p>3. Formation of a baseline list of Moroccan regulators, operators and manufacturers to be trained in program year 4</p>	Needs assessment underway and relationships established for upcoming workshops. Expected completion in Year 4.

2.4 SCHEDULE

The information related to the schedule of the different activities for the upcoming workplan will be included under section 6 of the relevant quarterly reports that will comprise this work year.

3. PROJECT MANAGEMENT APPROACH

3.1 ROLES AND RESPONSIBILITIES

The key roles for the SA2 project management team are that of Program Director, Program Manager, Program Administrator, and Private Sector Partner. These roles and their responsibilities are further defined below in Table 2 and Figure 1.

Table 2: Roles and responsibilities

ROLES AND RESPONSIBILITIES	
PROGRAM ROLE	OVERALL RESPONSIBILITIES
<i>Program Director</i>	Oversee the program to ensure the execution receives executive support and to align contract requirements. Manage recruitment of partners to ensure appropriate U.S. policies and positions are reflected in program activities and deliverables. Approve deliverables under the Branding & Marking Plan
<i>Program Manager</i>	Act as regional experts to undertake day-to-day execution of program work by using regional expertise, knowledge of international development, trade policies, standards and conformity assessment schemes. Includes monitoring of policy development, development of program deliverables, conducting of program activities and managing the project management resources as appropriately working with Program Administrators. Liaise with private sector partners as appropriate by region.
<i>Program Administrator</i>	Execute and carry out activities in line with contract requirements such as quality assurance, logistics organization and document management, facilitation of program review and feedback, reporting, and ongoing program support. Support for MEL plan and Branding Strategy/Marking plan implementation.
<i>Private Sector Partner</i>	Contribute staff time and expertise as available to participate in training or other activities in-country, presenting real-world examples and case studies to support training concepts. Some private sector partners will lead longer term initiatives supporting in-country engagement on a sustained basis and addressing an in- depth organizational or industry priority.

3.2 MANAGEMENT APPROACH

ANSI will implement a comprehensive and flexible resource management approach to plan, execute and manage the program. Any program roles and responsibilities that are expected of program team members and sub-grantees, such as team member assignments, reporting requirements, or meeting attendance, will be clearly assigned. ANSI proposes the following logical structure to outline the overall program implementation with any potential sub-grantees. (Legend: *ANSI-Implementing Partner; Sub-Sub-recipient*)

This logical structure will also serve a basis for the construction of a Work Breakdown Structure (WBS) for ANSI to ensure that program works are assigned with an accountable owner, through which program work and required resources will be accurately and realistically estimated and determined.

3.3 RISKS

Phase I of the Standards Alliance exposed ANSI to the global complexities surrounding the delivery of technical assistance related to NQI. Some of these risks remain present today and can negatively affect the impact and sustainability of SA2 cooperation. Among them are the concerted efforts by other developed and non-developed economies to increase their influence over developing countries' NQI related policies, including their views on the implementation of the WTO TBT Agreement; domestic idiosyncrasies related to the structure of NQI systems and the development and adoption of standards; the significant resources that other economies are directing to NQI technical assistance that can dilute the value of SA2 contributions; existing NQI systems or policies that were implemented as a result of that technical assistance from other economies; and, the lack of appreciation by recipient countries of the value of having the U.S. private sector engaging in NQI technical assistance.

In addition, the COVID-19 pandemic presented new risks associated with the SA2 holding events and traveling to partner countries. While actively monitoring CDC, WHO and USAID guidance in response to the pandemic, the SA2 will also explore alternative formats for Year 3 activities, including remote and virtual meetings, utilizing local experts, and increased desk research.

The proposed activities in this work plan for Year 3 have been conceived keeping these risks in mind and with the purpose of mitigating them. In addition, the SA2 will carry out yearly strategic planning sessions to further inform its field work and strategic framework. USG agencies, as well as private sector partners, will be invited to attend those different meetings.

4. PERFORMANCE INDICATORS

The following table shows information for the indicators that are applicable to Year 4 activities. For a full description of SA2 performance indicators and the Results Framework, please consult the SA2 Monitoring, Evaluation, and Learning Plan (latest version dated: August 8, 2020). Specific targets will be augmented with input from sub-awardees, and results will be reported through Monitoring and Evaluation reports.

	Indicator	Frequency
1.	<i>Countries have developed their national quality infrastructure.</i>	<i>Annual</i>
2.	<i>Number of trainings conducted about the value of using their national quality infrastructure</i>	<i>Quarterly</i>

	Indicator	Frequency
3.	Number of new international standards activities in which country participates.	Annual
4.	Number of international standards adopted or referenced by partner country.	Annual
5.	Countries have an enabling environment for a national quality infrastructure.	Annual
6.	Number of private sector participants in regulatory development project activities.	Annual
7.	Number of participants in national technical committees.	Annual
8.	Number of U.S. industry WTO TBT concerns with partner countries eliminated.	Annual
9.	Number of workshop/reserve trade mission participants	Quarterly
10.	Number of host-country COVID-19 preparedness and/or response plans in various phases (formally proposed, adopted, or implemented) supported with USG assistance.	Annual
11.	Number of trade facilitating procedures implemented during CV-19 with USG assistance.	Annual
12.	Number of laws or regulations proposed, adopted, or implemented to facilitate trade during CV-19 with USG assistance. .	Annual
13.	Number of WTO TBT and SPS notifications submitted by partner countries .	Annual
14.	Number of countries with transparent national quality infrastructure practices .	Annual
15.	Countries have shared their annual national standards Workplans	Annual
16.	Number of measures implemented to promote gender equality	Annual