Standards Alliance: Phase 2

Annual Narrative Report

Year 5 July 12, 2023 to July 11, 2024

Submission Date: October 1, 2024

Version: 1

Agreement Number: 7200AA19CA00012
Activity Start Date and End Date: July 12, 2019 to July 11, 2026
AOR Name: Daniel Vazquez

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

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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 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, The Inteleos Foundation
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, Ghana, Kenya, Mozambique, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	July 12, 2023 – July 11, 2024

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.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative – Year 5

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 (Y5). For greater details on each year of the activities the reader may refer to the quarterly reports developed by ANSI (Q3/4 2023, and Q1/2 2024).

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 launch and implementation of the COVID-19 Medical Device and Regulatory Convergence (MDRC) project and the finalization of eight (8) sub-award agreements with USAID approval. MDRC launched 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/*), which will continue to be updated throughout the rest of the program.

In Year 3 the Standards Alliance Phase 2 reached full implementation with training and other workshops being carried out across all activities. One of the MDRC's key accomplishments during Year 3 was publication of 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. Other noteworthy accomplishments included two successful workshops on petroleum standardization, allowing for a better understanding of relevant ASTM International standards; ANSI's partner Pivot forging a working relationship with ARSO and being able to begin implementing a 5-part workshop series on Bioethanol fuels; and NSF and AWWA

carrying out training in India and Brazil, respectively, so those two countries may achieve better safety and health standards benefiting the local population, which can then be more active in building the economy of the country.

During Year 4, ANSI and USAID secured an extension and ceiling increase for the overall program for two additional years; allowing for new activities to be implemented in Year 5 and Year 6 of the program. The SA2 program will focus the new activities that will be developed from 2024 to 2026 in the critical minerals, agribusiness, automotive, digital infrastructure, water and sanitation, and medical devices sectors.

Moreover, in Year 4, the program also carried out successful culminating events for activities with ASTM and Pivot. ASTM held an in-person workshop in Dakar, Senegal, and a Study Tour in Denver, CO in conjunction with ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants. The team also developed a stronger presence in Africa via a dedicated Africa Liaison under the MDRC project which allowed for the preparation of a regional training event on Good Regulatory Practices that will be further described in the paragraph below.

In Year 5, the early focus of the work was on the MDRC regional training activities in Africa in November 2023. These two workshops in Kenya and South Africa gathered key stakeholders from both the public and private sector, pushing forward harmonization around good regulatory practices for Medical Devices and concluded the capacity building part of the largest activity under the SA2 program.

During Year 5 several new activities also moved into the implementation phase. As mentioned above key sectors were identified in Year 4, and this reporting year saw the successful implementation of new activities in the health sector in Kenya focusing on ultrasound technology to combat maternal death, and also work in Senegal around bottled water certification. These activities and others directly implemented by ANSI within ISO are further illustrated later in this report as well as in the quarterly reports produced during Year 5.

2.2 Non-COVID-19 Related Activities Activity Implementation Progress

Global

Activity #13 – Support for critical minerals standardization coordination

In March 2023, ISO/TMB and the ISO Council approved and accepted the report 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.*

The SA2 program will support the work of the SAG on Critical Minerals and TC 345 through activities such as:

- Conducting awareness building to explore forming a U.S. mirror committee (TAG) to further bolster U.S. input and/or leadership in TC 345, 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.

During Year 5 ANSI managed a U.S. TAG and enhanced U.S. input and/or leadership in the activities of ISO/TC 345 by:

- Maintaining and updating the TAG website housing all the information related to the work of TC 345 for all US TAG members;
- Hosting biweekly meetings with the US TAG chair to continue coordination and planning;
- Continue to inform TAG members about the formation of the TAG. Including experts from the related TAGs for ISO committees on Lithium and Rare Earth;
- Using the IWA on Sustainable Critical Minerals Supply Chains as a tool for furthering the outreach efforts toward relevant stakeholders for the TC 345;
- Planned and conducted a U.S. TAG meeting to prepare delegation for 1st ISO/TC 345 meeting in Paris. The meeting took place in May 2024 and saw the adoption of Resolutions number 1 to 5 for ISO/TC 345. Said Resolutions aimed at further defining the scope and main functions on the TAG, highlighting for instance its strategic business plan, the main point of contacts for liaisons with other relevant technical committees, and the demand to establish ad hoc groups to study different proposals made under the tag such as:
    - A new ad hoc group, for Platinum group metals, to discuss the Chinese proposals introduced during the meeting regarding terminology, recycling and analysis and the potential overlap with ISO/DIS 19376-1 "Jewellery and precious metals
    - A new ad hoc group that will focus on gathering the requirements and needs involving other metals/minerals that would be similar to the ones highlighted by the Chinese proposals on Cobalt and Antimony, in particular measurements of majors and traces elements in metal and mineral compounds (ores, powders, ingots etc.).
- In a related but not directly project activity, the team also participated in a stakeholder call for ISO/PC 348 (follow-up to IWA Sustainable Critical Minerals Supply Chains), which was to identify a TAG administrator for that ISO PC.
- Finally, the team has also been holding monthly calls with US government stakeholders from the EPA and NIST to discuss the evolution of policy making around critical minerals.

Activity #17 – Promoting international standards for Management Systems for UN Sustainable development goals through U.S. leadership

During Q1 2024 ANSI added this activity to the Standards Alliance work plan. It aims at facilitating the adoption of a management system standard is a strategic direction for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives. The potential benefits to an organization of implementing such a standard for the UN Sustainable development goals are:

- Facilitating opportunities to enhance stakeholder satisfaction
- Enhance the opportunity to become a preferred partner
- Increase credibility enhancing the chance for getting; e.g. better external financing

- Addressing risks and opportunities associated with its context and objectives
- Avoid SDG-washing
- Enhance confidence
- Enhance the organization's performance
- Fulfil compliance obligation
- Achieve selected SDG objectives
- Increase success
- Create trust and confidence to relevant existing and future stakeholders.

Given ANSI's unique position as the US ISO member, and experience coordinating stakeholder input across a variety of priority sectors this activity has been supporting, a U.S. TAG for ISO PC 343 was established in early 2024. This is to enable U.S. contributions toward its international outputs; and work with U.S. government agencies and the private sector to align future work within ISO with U.S. policies and positions.

ANSI held a virtual PC 343 US TAG meeting in early 2024. The purpose of the meeting was to discuss the TAG member comments on the draft document, ISO WD 53001.3. The TAG Chair facilitated the discussion with TAG members and as a result, comments from 7 TAG members were submitted to PC 343/WG 1 for consideration. PC 343/WG 1 is expected to circulate an updated Working Draft in September.

ANSI has published various news articles and utilized social media to recruit new TAG members and expand the U.S. stakeholder group contributing to the work of PC 343. The website created for the US TAG to PC 343 which contains a repository of PC 343 documents and all emails sent to TAG membership (https://connect.ansi.org/isot/isopc343/SitePages/Home.aspx) is still available and continues to be updated as needed.

Also, during Q2 2024, ANSI staff members Sally Seitz and Steven Cornish met with the US TAG Chair to discuss the ISO/UNDP Memorandum of Understanding. This document outlines how the UNDP will participate in ISO PC 343. While the discussion at this meeting highlighted that the MOU does have some concerning language, the MOU was approved at the September 2024 ISO Council meeting in Colombia, and signed by the ISO Secretary General and UNDP. ISO plans to have a training session on the MOU and its implementation with PC 343 members during Year 6 of the Standards Alliance.

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

This activity was originally completed in Q3 2022 and carried out trainings in Year 3 in the Togo and

Gambia featuring an introduction to bioethanol, adjacent sector impacts, the importance of smart policy and standards, implementation of bioethanol projects, and a panel discussion followed. During Year 4 the work focused on connecting relevant parties in Togo and The Gambia (such as ATN and TGSB) with ASTM and relevant standards so they may access E3050 once it is approved and encouraging review for adoption, and partnerships via a Memorandum of Understanding (MoU) between the local standards organizations and ASTM to give them access to the standard.

Building on the success of the work in West Africa, in Year 5 Pivot began development of a five-part webinar targeting a continental audience, and focused on bioethanol as an alternative to toxic fuels like wood and charcoal that are commonly used for cooking on the African continent. Pivot is now coordinating with ARSO to implement the long-term lessons learned during the training.

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

Partner countries: Continent Wide

This activity was completed in Q3 2022 with the Personal Care Product Council (PCPC) working to develop a training series to support the harmonization of African personal care and cosmetics standards.

On February 28, 2023 PCPC and ANSI held the final webinar on Good Manufacturing Practices for Cosmetics. For the final webinar experts from PCPC continued to underline the importance and role of consumer protection in assuring compliance with labeling requirements set by cosmetics industries. Speakers expanded upon labeling practices for cosmetics in the U.S., EU, and Africa and provided top-level insight into aspects of labeling harmonization, eliminating barriers to trade in cosmetics and enabling the African Continent Free Trade Area (AfcFTA).

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

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 (Please refer to Q2 2022 for a detailed list of the research questions). 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.

In Year 4, CWSC expanded the list of their stakeholders to interview by requesting assistance from ANSI and from the USAID Missions in each partner country. ANSI provided valuable national standards body staff contacts and the USAID missions provided government contacts and appropriate Mission staff to interview. (Please see the list of stakeholders interviewed in Q3 and Q4 2022 report).

During Year 5, CWSC and IAPMO completed the Trend Report "Plumbing the Depths: An Analysis of NQI WASH in Ghana, Uganda, and Zambia." The Report analyzes and evaluates drinking water and sanitation laws to determine whether they are sufficient to enable an effective National Quality Infrastructure (NQI) for WASH in target countries. Ultimately, the research reveals several gaps within WASH laws and standards that suggest opportunities to improve the national quality infrastructure (NQI) for Ghana, Uganda, and Zambia. Two findings in particular demonstrate gaps in countries' commitments to WASH. First, neither the Constitution nor any other law in Ghana, Uganda, or Zambia establish human rights to water and sanitation. Second, limited WASH standards have been adopted to ensure that WASH products and services are safe and reliable, and even fewer are compulsory standards. These gaps present key opportunities for strengthening the sector and the report offers suggestions for how WASH laws can be strengthened. Countries can recommit to improving access to water and sanitation by establishing meaningful, tangible human rights to water within their Constitution or water law, as well as requiring the adoption of compulsory WASH standards to govern plumbing fittings and fixtures, piping, and water quality and water treatment technologies. The report provides additional findings and recommendations.

Finally, to conclude the activity CWSC, IAPMO, and ANSI hosted a webinar for more than 60 registered participants from Ghana, Uganda, and Zambia in WASH sectors across private, government, academic, and non-profit organizations to celebrate the launch of the report. Thirty-two participants attended the workshop and were engaged throughout the event, which took place on February 21, 2024. The report can be read here and the webinar can be found here.

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 works with peer group cohorts drawn from the staff of water sector utilities

in 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. This workshop series comprised of 2 virtual workshops, which included two follow-up calls each, and a final in-person workshop that took place in Zambia on April 25th and 26th 2023.

In Year 4, AWWA conducted a needs assessment survey which was distributed to utilities and other water and wastewater industry organizations in Zambia, Malawi, and Lesotho by AWWA's partners at RockBlue. Twenty-two 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. All stakeholders indicated they work in drinking water. Of the stakeholders, 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. Although 21 out of 22 stakeholders responded that they currently use some standards in their organization, a majority noted use of national standards rather than international standards. Just three participants were aware of AWWA standards before the trainings.

In ranking their interest of AWWA Utility Management Standards, the group of standards on drinking water management (G100, G200, G300, G480) was first, followed by a tie for the second highest interest of wastewater management standards (G510, G520) and the general utility management/business practices standards (G400, G410, G420).

As a result of the Needs Assessment engagement and further outreach, 35 individuals representing 17 organizations in Lesotho, Malawi, and Zambia officially registered as participants in the workshop series. The virtual workshops were around 3 to 3.5 hours long each day. The first virtual workshop for the Africa trainings was held on September 7th and 8th. Follow-up monthly check-in calls were held on October 12th and November 15th. The second virtual workshop took place January 10th and 11th. Monthly check-in calls took place February 7th, and March 16.

The third and final workshop took place April 25 and 26, 2023 in Livingstone, Zambia. Twenty-two participants attended in person, including an ANSI representative. The workshop included a full day of classroom instruction, a tour of the nearby Southern Water and Sanitation Company utility's treatment plant on the morning, and final classroom training and recognition of participants. All participants received a certificate of training completion.

This activity was completed at the end of Year 4 and the final report is included in the quarterly report for Q1 2024.

Activity #14 – Standards for Bioethanol Household Energy in Africa (STAND4BE)

Partner country: Mozambique

During Year 5 as the activities with West Africa and ARSO drew to a close (see Activity #1), Pivot submitted a new concept note for biofuel standards training, this time in Mozambique, and received Mission concurrence from USAID in Maputo in September 2023.

Consequently, ANSI and Pivot organized a two-day capacity-building training in Maputo that same month, which was hosted in collaboration with the National Institute for Normalization and Standards (INNOQ) and provided an opportunity for bioethanol energy and standards experts from Mozambique and the United States to share international best practices and policies for bioethanol standards development, both in the clean cooking and transportation sector.

The workshop aimed at introducing the following points:

- Introduce bioethanol as an economic driver in line with the Economic Stimulus Package that includes biofuels blending goals
- Provide technical assistance and determine a pathway for adopting ASTM E3050
- Tour a clean cooking business for a first-hand look at implementation to inform policy makers, government, and private sector
- Build awareness and understanding of relevant international standards for bioethanol quality, safety, and management systems
- Discuss the adjacent sector impacts on health, environment, climate, and related socio-economic considerations
- Engage with members of relevant ministerial committees, the private sector, and standardization bodies to dialogue around the next steps for implementing appropriate regulatory frameworks

The workshop was designed to support the development of Mozambique's bioethanol economy through blending mandates and other related goals stated by the government and specific to the August 2022, Economic Acceleration Stimulus Package (PAE). The SA2 workshop was well-timed to the launch of the PAE, and allowed for the SA2 team to work together with the US Department of Commerce in Mozambique to pursue ways of implementing the biofuels strategy. Pivot has been leading policy discussions with a group of stakeholders over the last year, which allowed the SA2 to structure the event with a greater awareness of dynamics in the country, and make connections that were beneficial to workshop implementation.

The final objective of this activity was to create a clear pathway for the adoption of ASTM E3050. Building on this effort, Pivot also followed up with the Ministry of Energy regarding agreements that would allow for capacity building, technical assistance, and knowledge transfer over the next three years in Mozambique. An MoU between U.S. Grains Council (USGC), Pivot, and the Ministry of Energy has been created, and approved by Pivot, USGC, and the Mozambican Ministry of Foreign Affairs. This document has been translated, and awaits an official signing of the MoU in Mozambique at the time of drafting this report.

Activity #15 – Supporting localization through the implementation of ISO 37101: Sustainable Development in Communities — Management System for Sustainable Development (MSSD)

Partner country: Cote d'Ivoire – Project closed

During Year 5, the SA2 began development of an activity centered around Management System Standards for Sustainable Development after receiving a request from the Government of Cote d'Ivoire to continue work previously conducted under SA1. A project plan was created that included roundtables and workshops with government stakeholders, as well as pilot communities in Cote d'Ivoire. The project consultants continued to work to develop two separate agendas for the planned two events – government policy roundtable #1 and pilot community workshop #1, including recruiting government and private

sector speakers and developing PPT presentations. However, after many logistical delays and despite the best efforts of ANSI and the project consultants, these trainings were unable to go forward.

Based on the repeated significant hurdles with the key public sector partners in the lead-up to the workshop and roundtable event days, ANSI and USAID, along with the project consultants, decided to close this activity. ANSI drafted a letter and shared it with USAID in Q2 2024, including the Mission in Cote d'Ivoire, for future transmission to the local partner.

Activity #16 - Improving Point-of-Care Ultrasound Access (IPOCUSA): Better Maternal Outcomes through Ultrasound Education, Workforce Development, Policy Advocacy and Certification

Partner country: Kenya

During Year 5, the SA2 launched a new activity focused on ultrasound education for the healthcare sector in Kenya; partnering with the Inteleos Foundation. The goal of the activity is to develop a curriculum and certification to equip learners with the requisite knowledge, skills, attitudes, and competencies to utilize the Obstetrics Point of Care Ultrasound (O-POCUS) effectively within their respective scopes of practice. This curriculum not only addresses the immediate need for improving maternal health outcomes but also recognizes the broader context of maternal and neonatal mortality as a persistent public health challenge in Kenya. By expanding the utilization of O-POCUS and mainstreaming it within the Kenyan healthcare system, the Kenyan Ministry of Health (MOH) endeavors to ensure its sustainability and accessibility across level 2-6 healthcare facilities, thereby contributing to the realization of UHC objectives.

The rationale behind this policy and curriculum lies in the necessity to bridge the gap between the demand for ultrasound services and the availability of trained personnel, particularly in rural areas. While O-POCUS does not replace standard ultrasound imaging, it empowers healthcare professionals to make informed clinical decisions to enhance efficiency and effectiveness in maternal health services.

This policy and curriculum serve as a standardized framework that not only harmonizes existing training programs but also guides institutions involved in training maternal healthcare professionals in O-POCUS. Inteleos has actively participated and contributed to both the policy and curriculum development national task forces.

Under this reporting period the team partnered with the National Nurses Association of Kenya and hosted a national webinar attended by 300 health professionals, building awareness on the upcoming policy and its translation to clinical practice. During Q2 2024, Inteleos secured a partnership with University of Nairobi and is in discussion with the Global Institute of Ultrasound, Imaging the world and KMET. This is building on implementation planning at scale for both in public and private sectors. A baseline research survey document has been reviewed and approved by the Kenya Association of Radiology and is pending endorsement by the Ministry of Health.

Activity #18– BW+ (Bottled Water Plus) - Bottled Water Certification Scheme for Senegal

Partner country: Senegal

NSF and ANSI began the Bottled Water + project on May 13, 2024. NSF conducted internal kick-off meetings with the three NSF program areas involved in the project: Beverage Quality/Food, Laboratory,

Food Sustainability Advisory Solutions; and externally, with ANSI and ASN. These meetings provided introductions and outlined next steps for the project.

Under this reporting year the activity has started a gap analysis, to be informed by the ISO/IEC 17065 needs, and ASN shared all documentation related to their current ISO/IEC 17065 accreditation and ECOSTAND 022 program. This included information on current document storage practices and resources, ISO/IEC 17065 accreditation administration and scope, all internal and external forms, training documents, Standard Operating Procedures (SOPs), lab documents, information on document storage. Moreover, NSF's Beverage Quality and Laboratory team members initiated a review of ECOSTAND 022 (in English). NSF's Beverage Quality/Food team has asked ASN if they are able to provide a list of documents referenced in in ECOSTAND.

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 Standards 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.

In the second part of Year 3 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 Directors General of the national standards bodies of 3 out of 4 SA2 partner countries for this activity. Ghana[1], Nigeria, and Senegal were all supportive of the program and endorsed its objectives.

During Year 4, implementation of this activity continued with two more in person events. The first was a workshop for eight focal points in Dakar, Senegal, from March 20-22, 2023. Both public and private sector stakeholders participated and the training included a visit to the Société Africaine de Raffinage (SAR) refinery and the local SGS laboratory. During the workshop the Secretary General from the Senegalese

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

Ministry of Petroleum and Energy delivered a welcome speech, as did the Director of the Senegalese Standards Body (ASN) and the Deputy Director from the USAID Office of Economic Growth. The Event also received coverage by local Senegalese Press: https://afrikbreakingnews.com/2023/03/21/normes-petrolieres-en-afrique-de-louest-une-3eme-formation-des-intervenants-a-dakar/. The second and final event in Year 4 was a Study Tour in the U.S for eight focal points. The Study Tour was successfully held in Denver, Colorado from June 24-29, 2023. At the end of the Study Tour, a debriefing session delivered by ANSI staff, was held to capture lessons learned and success stories from the 3-year project.

As mentioned above the Study Tour took place in parallel with ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants, which helped contextualize further the activity's work within the petroleum standard development field. During the duration of the Technical Committee, the designated project focal points came together to discuss applicable ASTM and API standards and testing protocols all the while attending key sessions of the Technical Committee such as Standards Writing, Proficiency Testing, Statistical Quality Control, Recycled Products Standards, and Official Voter Registration. The study tour also included a site visit to Peak Petroleum where the project focal points inspected various testing equipment, witnessed practical demonstrations, and spoke with lab technicians about testing method challenges for petroleum products here in the US. The focal points were able to witness the ASTM International standards development process firsthand. The active engagement of members throughout the standard-setting process is central to ensure their quality and relevance; and help them build more success stories to report to the SA2 program before its closing in 2026.

With the successful implementation of the Study Tour, this activity concluded and final reporting was shared in Q3 2023.

During the post implementation phase of this activity, representatives from Senegal and Ghana participated in the December TC meetings of ASTM Committee D02 on Petroleum. One focal point representative from Senegal's national refinery attended the meetings, and one supervisor from Tema Refinery in Ghana traveled for the meetings at the recommendation of the project technical consultant from Bureau Veritas, Ghana. During these meetings, Senegal's focal point met with the second vice chair of ASTM Committee D02 and vice chair of the D02 executive subcommittee, who provided more technical guidance on Research Octane Number (RON) between sampling and analysis. This guidance will help Senegal's national refinery, the Société Africaine de Raffinage (SAR), pinpoint the factors contributing to the decrease in octane rating between the point of sampling and the final analysis.

Furthermore, early this year, Senegal's focal point reported that due to the 3-year Standards Alliance Program, there has been increased integration of ASTM standards in the SAR's lab, and the refinery is considering participation in ASTM's Proficiency Testing Program. The focal point also conducted specific technical follow-ups with a D02 technical committee member and fuel expert about a project to replace manganese as a booster in Senegal. Senegal's focal point has also followed up with ASTM about attending the June 2024 D02 committee meetings and a possible refinery tour in Texas.

At the regional level, ECOWAS continues to use ASTM standards in the gasoline and diesel specifications for parameter analysis. Also, early this year Senegal's focal point convened a meeting with ECOWAS staff to discuss the possibility of ECREE signing an MOU with ASTM International. As a result of that meeting, a draft MoU was provided for review and is expected to be signed soon. Furthermore, the Director General of Senegal's national standards body, ASN, reported that ASTM standards for petroleum will be under consideration for inclusion in the new Senegalese Standardization Strategy, which is currently under development.

Finally, one focal point (industry rep) from Nigeria attended the "Alliance for Empowering Women"

gathering and ASTM D02 technical committee meetings in June 2024. Cote d'Ivoire's focal point (industry rep) reported that his organization is working on the adoption of the ECOWAS directives relating to fuel quality, for which ASTM standards are the main recommended standards. He has also enrolled in some of ASTM's online member training and plans to participate in the ASTM D02 Committee meeting in December 2024.

Activity #6 Africa Concrete and Building Code Adoption Initiative

Partner countries: Kenya, Tanzania, Uganda – Project closed

In 2021, ANSI worked with the American Concrete Institute (ACI) to develop this activity which aimed 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.

The activity, however, faced significant challenges in Kenya, Uganda, and Tanzania, due to a lack of familiarity with ACI standards.

During Year 4, ACI took the following steps to investigate a new strategy to see whether it would be worthwhile to propose a new subaward, as their original contract came to an end at end of 2022:

- **Research appropriate organizations (mainly engineering associations) who might be interested in partnering with ACI.** The Federation of African Engineering Organizations (FAEO) was identified as the perfect partner for ACI. The signing of an International Partner Agreement with FAEO was carried out in October 2022. ACI attended the conference as part of their fact-finding research to revise their strategy and to also solidify contacts and plans for an updated proposal. In late Q3/ early Q4 ACI proposed some changes to their upcoming activities and target countries. In response, USAID provided some feedback on the suggested changes which indicated that a more thought-out approach would be necessary to justify extending their project. The trip to Kigali helped confirm their new approach and solidify the necessary relationships.

- **Leverage Nigerian contacts made at the online ACI Seminar in August 2022.** Particularly the Federal University of Technology who introduced ACI to the Council of Registered Builders of Nigeria (CORBON), and after several virtual meetings, both parties agreed to sign an International Partner Agreement (IPA) in November 2022. Since CORBON is empowered to regulate the practice of building construction, maintenance, and management in Nigeria and also to regulate and control the practice of the building profession in all its aspects and ramifications, it became clear that establishing a relationship is in the best interests of both parties. CORBON has communicated to ACI that they are interested in the ACI Certification Program and ACI University to increase concrete knowledge throughout Nigeria.

- **Participation in the December 2022 Big 5 – Dubai Exhibition.** On the opening day of the event, ACI President and the team participated in the Big 5 Global Construction Leaders' Summit and garnered strong interest in collaborating with ACI for the adoption of its Code.

Despite ACI revising and adjusting its strategy for Africa, ACI continued to struggle to gain traction to move its project forward. Although it believes that the lessons learned, established working relationships, and solidified activities can help yield more tangible outcomes and benefits for beneficiaries in Africa in the future, ACI opted in June 2023 not to propose a new subaward. They did share a final report highlighting the outcomes of this sub-award activity which is included in full as an annex of this report during Year 4.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

Through this project, IAPMO works 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.

During Year 3, IAPMO convened several meetings to formulate the new faucet standard with National Standardization of Agency of Indonesia (BSN) and related stakeholders. At the end of Year 3, the draft faucet standard was released for public comment. In Year 4, comments were resolved by the BSN technical committee. Following, SNI 122:2022 was officially published by the National Standardization of Agency of Indonesia by Head of BSN Decree No. 213/KEP/BSN/7/2022 on July 18, 2022. The standard references several international standards as the foundation for its technical requirements: ASME A112.18.1/CSA B125.1, ASTM B117, ASTM B571, ASTM D3359 and ASTM D968. Additionally, the standard covers 15 product categories of fitting supply and replaces the old standard which was SNI 0122.

Development was of the new SNI was achieved with the following milestones:

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 – YEAR 4		ONGOING
2	Implementation of Mandatory SNI – YEAR 5		

2.1	Preparation of Risk Impact Analysis (RIA)	RIA	DELAYED
2.2	Meeting on RIA with Ministry of Industry		DELAYED
2.3	Proposal on the implementation of mandatory SNI to Minister of Industry and BSN	Proposal	DELAYED
2.4	Drafting of certification scheme	SK Menteri Perindustrian	DELAYED
2.5	WTO Notification	Notice	DELAYED
2.6	Establishment of SK Pemberlakuan and Penunjukkan LSPro and Lab	SK Pemberlakuan	DELAYED

Since the adoption of the standard, PT IAPMO Group hit an important milestone at the end of Year 4: Its faucet testing laboratory has full capabilities to test to SNI 122:2022. The lab's accreditation by KAN is still pending, but expected by the end of 2024.

Work on the implementation of a mandatory SNI, scheduled for Year 5 has been delayed. The Ministry of Industry has let IAPMO know that they would like time for the SNI 122:2022 to be normalized with Indonesian manufacturers prior to taking steps to make it mandatory (including the RIA). While no set timeline has been given by the Ministry, IAPMO is working to build local support for the implementation of the new standard to be made mandatory. This includes encouraging Indonesian manufacturers and distributors to certify their relevant products to the new standard who are reluctant to do so without the standard being made mandatory. IAPMO held a number of productive meetings with manufacturers and distributors during its delegation visit to Indonesia in Q2 2024 with most of these discussions ongoing. As part of this effort, IAPMO has continued to collaborate the Indonesian Plumbing Association (APIN) on the implementation of SNI 122:2022. IAPMO joined PERPAMSI (Association of Indonesian Drinking Water Companies) in November 2023 to broaden the coalition of support for this effort. In January 2024 an article was published in PERPAMSI's magazine to raise public awareness of this effort. Recipients of this magazine include water companies, city managers, and other government and industry stakeholders.

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

Partner country: India

During Year 3, AWWA completed the India Needs Assessment (please refer to Year 3 Annual Report for more information). AWWA also completed the first virtual workshop in April 2022.

In Year 4 of this activity, AWWA conducted two virtual workshops and one in-person workshops 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 were developed and conducted through a collaboration of AWWA staff, water utility Subject Matter Experts (SMEs) and local partner AWWA India to tailor content for the specific regional audiences. The 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 India.

The second virtual workshop took place in India on July 20-21, 2022. The virtual workshop lasted approximately 3-1/2 hours on each of the two days and was attended by 19 participants representing 8 Indian water and wastewater utilities. All attendees were provided with pdf versions of the two ANSI/AWWA Standards to be covered in the workshop series (ANSI/AWWA G100 – Water Treatment

Plant Operation and Management and G520 – Wastewater Collection System Operation and Management). Follow-up monthly check-in calls with the Indian participants were held on August 17 and September 22, 2022.

AWWA's third workshop in India was held virtually on October 18, 2022. The workshop lasted approximately 3-1/2 hours and was attended by participants from 7 organizations and included 15 individual participants from Indian water and wastewater utilities. All attendees were provided with pdf versions of fifth ANSI/AWWA Standards to be covered in the workshop series (ANSI/AWWA G510 – Wastewater Treatment Plant Operation and Management). A follow-up monthly check-in call with the Indian participants was held on November 9, 2022.

The final workshop, held in person in Varanasi on December 5-6, 2022 was attended by 17 individuals from 10 utilities in India. Workshop attendees also participated in the concurrent AWWA India Annual Conference for water industry professionals. The workshop was held over two days for approximately 2-1/2 hours per day. Attendees received hard copies of all 15 of the ANSI/AWWA Utility Management Standards and received a framed certificate for attending. A group dinner was held following the second day of training.

This activity was completed at the end of Year 4 and a final report has been shared during Q1 2024.

LATIN AMERICA

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

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

Partner country: Brazil

This project is intended to enhance 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.

NSF conducted a needs assessment to determine the guidelines and processes drinking water providers in Brazil. Please refer to the Year 3 Annual Report for the needs assessment summary. Additionally, the first webinar on NSF/ANSI/CAN Standard 61 was held in Year 3.

During Year 4 in Brazil, the NSF/ANSI/CAN Standard 60 webinar was planned and executed. This training was pre-recorded in Portuguese in September 2022 and played live in October 2022. The webinar included a live Question and Answer period, also conducted in Portuguese. The training 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/ANSI/CAN Standard 60 technical overview. The training was delivered to all stakeholder categories (regulators and health agencies, manufacturers, and consumers) concurrently. Fifty-two stakeholders attended the webinar live. In response to the webinars, stakeholders have requested the revision of the technical standard ABNT NBR 15784: *Produtos químicos utilizados no tratamento de água para consumo humano — Efeitos à saúde — Requisitos, which i* is the Brazilian national standard for evaluating the health effects of water treatment chemicals. ABNT NBR 15784 references both NSF/ANSI/CAN 60 and NSF 600 as its technical basis for chemical products to be used in the treatment of drinking water. The revision of the standard is expected to be completed in 2024.

NSF's workshops united various stakeholder groups, disseminating crucial information on drinking water standards and emphasizing the value of these standards within the context of regulatory bodies, manufacturers, and consumers in the region.

The project in Brazil was complete following NSF/ANSI/CAN Standard 60 webinar. However, throughout Year 4, NSF's team in Brazil continued to receive and respond questions raised by stakeholders in response to the webinars regarding the standards. Questions were primarily received from equipment manufacturers and water treatment and water utilities.

This activity was completed at the end of Year 4 and a final report was shared during Q4 2023. No further updates are available at the time of this report.

MIDDLE EAST NORTH AFRICA

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

Partner country: Morocco

This project is intended to enhance 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 provide the baseline for discussions with stakeholders.

During Year 4 in Morocco, the Needs Assessment and the training material for NSF/ANSI/CAN Standard 60 and NSF/ANSI/CAN Standard 61 was completed. The training included an introduction of the presenters, USAID, ANSI, Standards Alliance: Phase 2, and NSF International followed by the standards development process and its value and an overview of NSF/ANSI/CAN Standards 60 and/or 61. NSF conducted the needs assessment at the end of Q2 2022, please refer to the Q2 2022 quarterly report for details.

NSF's Morocco project leader met in-person with the Ministry of Health (MoH) early in Year 4 (August 2022). Morocco MoH leads the National Water Committee, where all in-country stakeholders active in the water sector are represented. During the meeting, the Morocco MoH expressed interest in the project and the potential to tie it to the Morocco National Water Committee's efforts. At the request of the Morocco MoH, NSF and the Morocco MoH entered into a formal partnership (Memorandum of Understanding) for the SA2 project in Morocco.

NSF coordinated the logistics for in-country training dates and venues. NSF initially planned these as 6 separate trainings) to accommodate identified individual stakeholder groups. However, MoH proposed that the trainings be held with all stakeholder organizations concurrently (not individually by organization) over a two-day period at their office in Rabat.

The MoH also conducted outreach and sent invitations for the training, most notably to the Moroccan National Water Committee. Furthermore, the MoH promoted the SA2 project and the importance of developing a local standard addressing the health effects of products, materials and chemicals used in the water sector. NSF was glad for the interest and support from MoH as it strengthened interest and participation for the event.

The in-person training on NSF/ANSI/CAN Standard 61 and NSF/ANSI/CAN Standard 60 was delivered October 19 and 20, 2022 respectively at Morocco MoH office in Rabat, Morocco. NSF representatives were on-site to provide the training and translation, and additional technical staff were available virtually.

The NSF/ANSI/CAN Standard 61 training had 23 attendees and NSF NSF/ANSI/CAN Standard 60 training had 21 attendees represented from key stakeholder organizations with participants from both the private and public sectors. Further, all members of the National Water Committee participated in both trainings, which created a space for discussion on how to adopt NSF/ANSI/CAN Standards 61 and 60 in Morocco.

Following the training in Rabat, NSF debriefed with the MoH. The Moroccan MoH indicated that there was interest in referencing and /or adopting NSF standards locally. As such, NSF held a follow up meeting in early January 2023 to elaborate on their technical advisory services and other ways NSF may be able to support Morocco community water initiatives, such as the concept of Water Safety Plans. This was mentioned specifically because, although there is no regulation in place for *Legionella* prevention in Morocco, according to the MoH, the concept of Water Safety Planning is gaining attention, including with the Moroccan National Water Committee. As a result, there was a recent introduction of a Water Safety Plan "guideline," which was shared in French and English with NSF.

Additionally, NSF has maintained engagement with the MoH to keep updated on the National Water Committee discussions and provide support to their discussion and initiatives, as requested. To this end, two virtual meetings with MoH's Rachid Wahabi, Chief of Environmental Health Division occurred in January and March 2023. Mr. Wahabi confirmed that National Water Committee is interested in referencing or adopting NSF standards although there are some difficulties identified by the Committee to have NSF requirements align with the local needs (further details are available in the Q1 2023 report).

This activity was completed at the end of Year 4 and a final report has been shared during Q4 2023. No further updates are available at the time of this report.

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

This activity has been complete since the end of year 3, at which time a final report was circulated. Notable outcomes were that 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.

Ethical Apparel passed the qualification testing for the surgical face masks they were trying to produce in Ghana. As a result, Ethical Apparel's surgical masks now meet the ASTM Level 2 Standard, and can now be produced in Ghana. Therefore, implementation finalized in the first quarter of 2023 after facing many delays. More details on the project will be included in the final report shared by EAA, attached in this report as an annex.

The next step was for a Quality Management System (QMS) EEA to be developed. At the close of the project GSA still needed to approve the QMS, get training on how to conduct it and the Ministry of Health needed to place orders for EEA to build the clean room and start producing the masks.

GLOBAL

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

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

Global

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 report published in 2022. 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.

In 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 levels.

In Year 3, MDRC continued its engagements at the local, regional, and global levels to promote GRP in medical technology regulatory frameworks. MDRC observed that the lack of proper legal foundations (GRP) and the inappropriate use and application of regulations for medicines to craft medical technology regulations significantly undermine medtech regulatory convergence. MDRC further noted that many regulatory bodies have limited staff exclusively dedicated to medical devices, and so prioritizing training on reliance and regulatory convergence, rather than on resource-heavy processes that may cause trade bottlenecks – such as dossier reviews – is critical.

Throughout Year 4, MDRC leveraged several global platforms to advance its workstreams. For example, MDRC engaged in the open stakeholder activities of the International Medical Device Regulators Forum (IMDRF) in Sydney, Australia in September 2022 and organized multiple meetings with MDRC and MDRC partner national regulatory authorities (NRAs) on the sidelines of the IMDRF meeting held in Brussels, Belgium in March 2023. Such engagements provided an opportunity for MDRC to structure its capacity building to respond to NRA partner requests and to maximize programming in conjunction with other global MedTech activities.

Additionally, the Inter-American Coalition for Regulatory Convergence in the MedTech Sector (the IACRC or "Coalition") operated in its capacity as lead MDRC global implementer of Tier One and Two workstreams by organizing project engagements with global organizations such as the World Trade Organization (WTO) and World Health Organization (WHO) in Geneva. These engagements enabled MDRC to increase global awareness of the importance of compliance with international obligations in resolving technical barriers to trade (TBT), regulatory bottlenecks, and related challenges to the MedTech sector – especially in the context of COVID-19. In October, MDRC was recognized by Deputy United States Representative and Chief of Mission (Geneva) María Pagán at the World Trade Organization Symposium on Technical Barriers to Trade. Ambassador Pagán highlighted the project's work "conveying assistance to 10 partner countries across Latin America, Africa, and Southeast Asia to increase the transparency and predictability of regulatory systems for medical devices by providing technical assistance on good regulatory practices."

During Year 5, the final year of implementation of the activity, the work included a regional event in Africa, which is furthered described under the relevant country's section of this report. The MDRC also focused

on preparing a final report as all other outputs were completed by the end of Year 4. The MDRC Final Report is under review by AdvaMed and ANSI and will be submitted in October 2024.

Early under Year 5, during Q4 2023, MDRC advanced GRP in medical technology regulatory frameworks through engagements at local, regional, and global levels. During meetings with stakeholders, including ministries of health, regulatory coordinating bodies, national standards bodies, standards organizations, and regional trade associations, MDRC observed that the absence or lack of proper implementation of legal foundations, the lack of sufficient and skilled resources at the NRAs and inappropriate application of pharmaceutical regulatory criteria to medical devices and in vitro diagnostics (IVDs) constitute a barrier to advancing regulatory convergence. MDRC also highlighted that many regulatory bodies have limited dedicated staff for medical devices, emphasizing the importance of prioritizing training on reliance and regulatory convergence over resource-intensive processes such as dossier reviews, which can create medtech trade and health barriers.

During the same aforementioned quarter, MDRC supported project countries' efforts to conduct appropriate regulatory oversight while minimizing regulatory burden on industry through meetings held on the sidelines of the Medical Device Single Audit Program (MDSAP) 2023 Forum, which ANVISA hosted in Brasília, Brazil. MDRC meetings with USFDA, ANVISA, and COFEPRIS provided an opportunity to strengthen COFEPRIS's understanding of ANVISA's implementation of medical device regulatory best practices including standards and conformity assessment – with a focus on reduction of dossier review backlogs. The complementary participation of MDRC and COFEPRIS in the MDSAP Forum together with other global NRAs allowed COFEPRIS to hear from other reference authorities presenting overviews of regulatory updates specific to their countries and discuss utilization of the MDSAP program, which also contributed to their acceptance as a MDSAP Affiliate Member.

The MDRC through the Inter-American Coalition for Regulatory Convergence continued its engagement with the World Health Organization (WHO) to address future collaboration to advance MDRC recommendations and efforts to address WHO internal processes that are not aligned with WHO guidance for NRAs on GRP (See Section 2.4: Implementation Challenges). In December, MDRC attended the 11th Annual Collaborative Review Program WHO hosted in Doha, Qatar. These panels brought the Medical Device and IVDs sector to the conversation, by highlighting the critically necessary differentiation between pharmaceuticals and devices, as well as on GRP and the relevance of capacity building for their implementation. During this event, WHO acknowledged the need to revise its own internal implementation of GRP, including public consultation its own process to develop guidelines.

Latin America

Launched in Q2 2020, 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.

During Year 3, 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.

In Latin America during Year 4, the Coalition led MDRC's execution of key multilateral engagements and trainings to advance regulatory convergence efforts. For example, in March 2023 MDRC joined key stakeholders at the first convening of Americas RISE for Health under the chairmanship of the U.S. Department of Commerce and U.S. Department of Health and Human Services in Panama City, Panama. Overall objectives included building resilient, pandemic-prepared health economies and supply chains as well accelerating regulatory improvements. The agenda included a session on Good Regulatory Practices and Regulatory Improvements, for which MDRC provided concluding remarks.

The MDRC continued its progress on the development and implementation of the Coalition during Year 5. For example, the Coalition has coordinated with the Pan American Health Organization (PAHO) regarding Coalition engagement with the PAHO RED-PARF meeting of regional MedTech regulatory authorities planned for 11-13 October 2023 in San Salvador, El Salvador. These meetings provide a timely opportunity for MDRC to further its collaborations and advance MEL plan metrics with the MDRC national and regional partners with a focus on the establishment of international MedTech reference documents essential for regulatory convergence and COVID-19 response and recovery efforts.

Through these engagements, MDRC convened Tier One and Two public and private sector representatives from the project countries and broader region to:

- Encourage the implementation of best practices specific to medical device regulation and the utilization of internationally harmonized standards in the project countries.
- Facilitate the alignment of regulatory approaches and technical regulations in a manner that minimizes trade restrictions.
- Highlight the responsibility of health authorities in fulfilling trade obligations.

These engagements not only advanced important multilateral Tier Two objectives for the region but also complimented MDRC workstreams in each project country.

Brazil:

All of the relevant training in Brazil took place under the first four years of the activity leading an effort to formalize partnerships with local stakeholders to advance Tier One and Two objectives in-country. At Tier One, MDRC continued coordinating with the National Institute of Metrology, Standardization and Industrial Quality (INMETRO), the Ministry of Economy's Secretariat of Foreign Trade (SECEX) and Secretary for Competition Advocacy and Competitiveness (then SEAE, now reorganized as SCPR). These efforts were bolstered by the successes of the Summit of the Americas programming. At Tier Two,

partnered with The Brazilian National Health Regulatory Agency (ANVISA) the Brazilian Alliance of the Innovative Health Industry (ABIIS) to organize capacity building on strengthening vigilance around technology processes, practices, and regulations in post-market monitoring in Brazil. This capacity building complements MDRC's partnership with private sector stakeholders, such as the Latin American Alliance for the Development of In Vitro Diagnostics (ALADDIV).

In Year 4, MDRC continued to advance its workstreams in Brazil, particularly on the national adoption of ISO 15197:2013 - *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus* – in coordination with the Brazilian National Standards Organization (ABNT) CB-36 working group on the Internalization of ISO 15197:2003 – In Vitro Diagnostic Test Systems. MRDC also continued engagements with INMETRO to review the MDRC GRP/TBT checklist for its applicability as an INMETRO Standard Operating Procedure, and in Q2 2023, MDRC held meetings with the Ministry of Industry and Development – Division of Competitiveness and Regulatory Practices (MDIC/SCPR). MDIC colleagues suggested using the checklist as a pilot among regulators to verify compliance with GRP and TBT rules.

Colombia:

All of the relevant training in Colombia took place under Year 3 of the activity, from July to September of 2021, including:

- **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

During Year 4 of the project, the work focused on constant coordination and on-the-ground work by the Colombia Liaison and broader MDRC team continued the formal implementation and institutionalization of GRP in Colombia at both Tiers One and Two, laying the groundwork for trainings in Q1 and Q2 2023. During this time, the Ministry of Health was formally recognized in a national contest for its approval and publication of GRP requirements (including the PPE guide) for all Ministry regulatory processes in line with international obligations and reference documents. The U.S.-Colombia reciprocal PPE guides can be found in English here and in Spanish here. The U.S. version published by NIST can be found through its website here.

Mexico:

Following outreach in Years 2 and 3 of the activity, MDRC signed a Letter of Intent (LOI) with Government of Mexico. The LOI formalized a partnership to advance GRP, work towards regulatory convergence for medical devices, and leverage international best practices and guidance. This LOI provides the basis for MDRC's efforts to institutionalize GRP at the Tier Two level. MDRC also continued work with public and private sector partners to address specific regulatory non-alignments with international obligations.

During Year 4, MDRC continued its engagements with Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS) and the Pharmacopeia of the United Mexican States (FEUM) to address the lack of systematic compliance with Mexico's domestic legal and international treaty obligations GRP. In Q3 and Q4 2022 MDRC experienced delays in advancing its workstreams with COFEPRIS, including addressing trade concerns presented by NOM-241, but has diligently worked in Q1 and Q2 2023 to address trade bottleneck and access concerns.

NOM-241 entered into force 20 June 2023 and does not allow for the recognition by COFEPRIS of inspection audits of medical device manufacturing facilities consistent with international standards and Mexico's commitments under the USMCA. After MDRC's numerous meetings with COFEPRIS, the Ministry of Economy (SE) and the Mexican Embassy to the United States, COFEPRIS committed to take several actions, including to review NOM-241 in full. Until such review occurs, COFEPRIS issued interpretation criteria to mitigate some of the most critical issues. COFEPRIS issued two Official Notices ("Circulares") through the Sanitary Promotion Commissioner, but they do not provide sufficient legal certainty. Mexico's Minister of Economy requested the creation of a Task Force including SE, COFEPRIS, and representatives of the medical device industry to solve the technical and legal issues. SE also requested input from the industry on the legal pathways available to SE and COFEPRIS to modify NOM-241.

In October 2023, COFEPRIS issued the Strategy for Regulatory Certainty of the Medical Devices Sector which refers to MDRC contributions, the creation of a Committee of GRP as well as the GRP and CA Checklist. Additionally, COFEPRIS confirmed the formal submission of their application to become an affiliate member of MDSAP, which is a major milestone achieved through the years-long joint effort by COFEPRIS, USFDA, and MDRC. Finally, constituting a significant MDRC achievement, on 31 October, COFEPRIS submitted NOM-241 to the Ministry of Economy for inclusion for revision within the Mexican regulatory agenda for 2024.

Peru:

In Year 2 and 3, the Coalition conducted outreach with government ministries and agencies. Since initial outreach, MDRC has continued to coordinate with the USAID Mission to Peru and private sector stakeholders, setting the stage for MDRC to advance relevant objectives in the country. MDRC held regular meetings with those stakeholders to develop workstreams and schedule of trainings.

In 2022, under the ACR triannual Procedures Review the Peruvian ALAFARPE – AMCHAM Joint Committee for Medical Devices (CDMMAA), in alignment with MDRC, provided comments to address misalignments with international standards and references included in relevant procedures to approve medical technologies for commercialization in the country.

In Year 4 MDRC advanced progress on regulatory harmonization. MDRC continued engagements with the Peru Medical Device Joint Committee, the National Association of Pharmaceutical Manufacturers (ALAFARPE)-AMCHAM, to discuss turnover within Directorate General of Drug Supplies and Drugs (DIGEMID) and review the Analysis of Regulatory Quality. In Q2 2023, MDRC conducted an interactive training session with the Peruvian MD Joint Committee, keeping USAID informed on the ground, covering GRP concepts and country-specific items.

Africa

Following delays in the first years of implementation related to securing the Mission concurrences, MDRC conducted outreach to attempt to move the process along. Despite this outreach, MDRC experienced challenges in the formalization of the workstreams due to limited government engagement. At the regional level, MDRC established working relationships with the African Medical Devices Forum (AMDF) and the African Organization for Standardization (ARSO). MDRC partnered extensively with the private sector to generate a formal regional engagement mechanism that can coordinate industry efforts to drive medical devices regulatory convergence and GRP implementation across the continent. This mechanism was formally created under the GMTA and GDA as an Africa Working Group. The Working Group constitutes an African coalition for regulatory convergence in the medical technology sector – a significant MDRC MEL Plan milestone.

During Year 4, MDRC organized a two-part Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector in Africa. The workshop advanced both Tier One and Two workstreams in all three African Project countries. Additionally, MDRC laid the groundwork for a series of regional and continental trainings on GRP and implementation took place in Year 5, working in close coordination with FDA on the capacity building training curriculum. Marking a significant MDRC milestone, on 20 June the FDA signed off on the curriculum, which now constitutes the first ever FDA-industry developed "menu" of MD NRA training options from which to develop training sessions aligned with international reference documents and with an emphasis on GRP and use of standards. With inputs from South Africa Health Products Regulatory Authority (SAHPRA), Kenya Pharmacy and Poisons Board (PPB), Mecomed, FDA, and MDRC, the training curriculum is the first Medtech-NRA global level curriculum jointly approved by industry and government. The curriculum marks a significant MDRC output and will be a GMTA and IMDRF contribution.

MDRC also submitted a new budget proposal to reallocate resources to the Africa Liaison. The primary functions of the Africa Liaison include:

- **Role 1 (Kenya National Focus):** Provide dedicated support to MDRC partners in Kenya, principally with Kenya PPB, focused on national MEL plan implementation.

- **Role 2 (South Africa and Ghana Focus)**: Provide dedicated support to MDRC partners in South Africa and Ghana, principally with SAHPRA and the Ghana Food and Drugs Authority (GFDA), focused on national-level MEL plan implementation in those countries.

- **Role 3 (AMDF Focus)**: Provide support to PPB and SAHPRA in their roles leading AMDF and provide support to the AMDF Secretariat focused on continental MEL plan implementation.

In Year 5 following extensive coordination with AMDF members and partner NRAs – principally USFDA –MDRC held the MDRC-FDA-AMDF capacity building workshop on 6-10 November. Sessions incorporated the training curriculum co-developed by MDRC and USFDA – with critical input from stakeholders such as PPB and SAHPRA – and the workshop marked a capstone regional engagement for the project.

In preparation for the MDRC-FDA-AMDF workshop, MDRC conducted key meetings with session speakers and partners, including USFDA, the Medical Technology Industry Association of Kenya (MEDAK), global SMEs, the Association for the Advancement of Medical Instrumentation (AAMI), and AMDF to finalize the MDRC agenda, align messages, and secure participation from NRAs of Australia (TGA), Brazil (ANVISA), and Singapore (HSA) to share experiences on reliance.

Key takeaways and highlights from the session may be found under the relevant country sections below, with additional information in the November monthly report and the MDRC website.

Over the four-day continental workshop, the sessions were structured to cover a diverse range of topics, fostering knowledge exchange and collaboration among participants. The opening day commenced with welcoming remarks from distinguished figures from PPB, AUDA-NEPAD, and Africa CDC. MDRC set the goals for the week, emphasizing information exchange and capacity building among AMDF members, partner NRAs, Africa CDC, and industry. The subsequent sessions delved into crucial subjects pertaining to regulation of medical devices and international standards, including ISO 13485 and ISO 14971 conformity assessment. The day concluded with a recap by the AMDF Vice Chair, who stressed the importance of reliance and stakeholder engagement.

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.

At the end Year 4 (Q2 2023), GFDA signed the MOU, and the document is awaiting signature of all parties under the MDRC project, expected to be complete in Q3 2023. MDRC met with members of the Ghana Mission to share an overview of the work to date and MDRC's plans for the remainder of the year.

Given the initial pace of MDRC communications with the Ghanaian authority partners, MDRC opted to schedule MDRC Ghana workstream engagement following the MDRC-FDA-AMDF continental level training which took place in Nairobi, Kenya in November 2023, under reporting Year 5. The MDRC sponsored GFDA participation in the MDRC-FDA-AMDF training, met with GFDA together with USFDA,

USAID and ANSI while in Nairobi, and subsequently held a virtual follow-up meeting in December 2023, confirming plans to continue virtual training in 2024 as an MDRC legacy activity. As an additional output of the newly acquired knowledge, GFDA reported their interest to recognize ISO13485.

Kenya:

MDRC conducted initial outreach in Kenya in Q4 2021. Thereafter, MDRC worked with the Pharmacy and Poisons Board (PPB) to formally develop a dedicated Tier Two workstream. In Q2 2022, MDRC and PPB finally developed an MOU to formalize their partnership.

During 2023 during years 4 and 5, on the sidelines of regional trainings, MDRC held three events and many meetings with key public and private sector stakeholders in Nairobi. This included engagements with the Kenya PPB, AMDF, the Kenya Bureau of Standards (KEBS), African Organization for Standardization (ARSO), the Medical Technology Industry Association of Kenya (MEDAK), the Kenya National Chamber of Commerce and Industry, the AmCham Kenya, candidates for the MDRC Africa Liaison positions, the USAID Mission in Kenya, and the U.S. Foreign Commercial Service (FCS). PPB input was critical to the development of the training curriculum, and MDRC held frequent discussions with PPB to finalize the training schedule to meet regulators' needs and make the best use of available funds from U.S. government. The training curriculum was used for on-the-ground trainings in Nairobi in August 2023. The curriculum prioritizes agency capacity building for the strengthening of regulatory frameworks and processes.

In total, three events focused on capacity building were held in 2023 with the Pharmacy and Poisons Board (PPB) on the following thematic areas:

- GRP and medical device regulation Utilization of international standards and references
- Quality management systems–regulatory process and medical device manufacturing CA for medical devices
- Regulatory reliance
- Development of regulatory instruments and open public consultations –Gap Analysis
- Strategic Plan
- GBT+ – MDRC recommendations on GRPs CA streamline–PPB and KEBS coordination General recommendations on implementation of GRP & CA Checklists

Following the workshop, a specific workstream on enhancing the rule making process at PPB was agreed upon, including GRP obligations under the WTO/TBT which had not been considered. Another critical output was the decision to utilize MDSAP for ensuring medical devices are manufactured to the relevant international standard.

In November 2023, MDRC engaged PPB, KEBS, USFDA, MEDAK and IEC to identify opportunities to streamline the inspection processes and scope of responsibilities at PPB and KEBS.

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.

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. MDRC also worked with representatives from the Department of State, and USAID in D.C. 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.

In February 2023, SAHPRA and MDRC finalized all signatures on the Terms of References (TOR). The TOR formalized their partnership in executing Tier One and Two workstreams. With the TOR fully executed, MDRC could deepen its capacity building efforts in the project country during the next year of the SA2 program. In August 2023, the MDRC held a meeting with SAHPRA as part of the USTDA-organized meetings at AdvaMed in Washington, D.C. During the meeting, SAHPRA requested insights into how international standards affect local medical device manufacturers. Participants also explored the complex dynamics of treaty obligations in relation to domestic legislation and regulations, including considerations related to the WTO/TBT agreement. A significant point of discussion was the role of the Department of Trade and Industry (DTI) in resolving conflicts between SAHPRA and South Africa's trading partners in the context of these treaty obligations.

In November 2023, the MDRC in collaboration with SAHPRA organized a workshop utilizing the Medical Device Technical Assistance Training Curriculum. The WHO and NRAs from Australia, Brazil, and Singapore contributed to the development of competencies by sharing their experience on implementation of reliance and utilization of international standards. Experts from USFDA presented technical topics as well as on GRP and CA, the latter alongside SABS and the South African National Accreditation System (SANAS). Notably, the WHO recognized the impact and relevance of the MDRC's work.

The MDRC also engaged with SABS and SAHPRA in November of 2023 to reestablish the communication mechanism among the two institutions and to establish the proper procedures for South Africa to notify regulations produced by SAHPRA. A follow up meeting among the CEOs of the two institutions to formalize the agreements was committed. This timely engagement opened up the opportunity for the medical device regulatory framework under revision, to properly comply with GRP obligations.

Indo-Pacific

MDRC successfully secured USAID Mission concurrence and conducted formal outreach to government agencies in Vietnam and Indonesia, although as described below, stakeholders in Vietnam did not confirm their participation in MDRC activities. During Year 3 MDRC collaborated with the U.S. Department of Commerce International Trade Administration (ITA) to coordinate the future execution of a Tier Two regional training. MDRC held its first virtual regional Workshop on Good Regulatory Practices and Medical Device Regulation on 28 February and 1 March 2023. The workshop was organized in close coordination with the Association of Southeast Asian Nations (ASEAN) Consultative Committee for Standards and Quality (ACCSQ), ASEAN Medical Device Committee (AMDC), and the ASEAN Secretariat. The workshop featured discussions the World Trade Organization's (WTO) TBT agreement and legal obligations as it relates to GRPs and national commitments, assessment of safety and performance of medical devices; regulatory reliance models for medical device assessment; and post-market surveillance.

The team finalized its Stakeholder Mapping Reports in Q1 2022 which covers the Indo-Pacific region.

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. This was the first local capacity building event held by MDRC in Indonesia. The webinars were executed in collaboration with the Indonesian Ministry of Health and University of Gadjah Mada.

Throughout Year 4, MDRC organized hybrid, small-group discussions with Indonesian Ministry of Health officials covering foundational GRPs, Quality Management Systems (QMS), conformity assessment, and personalized medical devices. The latter topic was included at MOH's request. The MDRC team introduced the conformity assessment checklist and offered to work with officials on tailoring it to their needs. MDRC is currently seeking to support the Indonesian MOH in the revision of its SOP on medical device regulation, bringing in content from the GRP and conformity assessment checklists as needed.

Under the work of the MDRC, the Indonesian Ministry of Health began integrating foundational GRP into government processes. Throughout the project, capacity building exercises, namely the webinar series and small group discussions, increased understanding of GRP and the need to formalize GRP within government processes. The Ministry of Health requested support integrating GRP into their current SOP, which informs their approach to medical device regulation.

The MDRC supported the refinement of the SOP and integration of GRP. An additional opportunity for further impact arose given Indonesia's 2023 passing of the Health Omnibus Law, and the Ministry of Health also requested support to integrate some of the key articles of the new law pertaining to medical devices into the revised SOP, to make the latter a living document that can be used more prescriptively and in line with the new regulations. By incorporating GRP and new articles from the Omnibus Law, the SOP has the potential to improve the quality of medical device regulation in Indonesia over the long-term.

After establishing workstreams in each project country and developing a workplan, the MDRC focused on implementation during the final project years. In addition to convening NRAs and other public sector stakeholders, the MDRC recognized the importance of including the private sector perspective.

Higher levels of private sector participation can indicate increased awareness of regulatory and standards setting activities and potentially increased participation in these processes. With increased buy-in from the private sector, governments can have increased confidence that regulations will be effective in addressing regulatory objectives with market realities.

During training and workshop engagements, the MDRC also prioritized measures to promote gender equality, recognizing that awareness for the necessity of gender equality will help ensure the creation of polices that are inclusive and empowering for the country and foster the development of a more business-friendly environment.

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, in July 2022, Vietnam was unable to officially confirm its participation in the MDRC and did not respond to MDRC's queries on the procedural process for engagement. MDRC understands this is likely due to DMEC's limited resources and personnel and other competing priorities. Given project timelines and resource utilization requirements, MDRC made the decision, in Q1 2023, to redirect attention and resources from Vietnam to Indonesia, where there has been more intensive engagement.

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 SA2 activities have encountered those types of challenges and they have been highlighted in the relevant quarterly reports.

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

The CWSC uncovered limited information with respect to research questions #3 and #4 regarding additional barriers to NQI beyond those presented in environment and water-related laws and regarding workforce development.

Activity #7 – Increase the Flow of WASH Services

In order to mandate SNI 122:2022, there must be at least one Indonesian manufacturer whose product is certified to this SNI. IAPMO continues to collaborate with the Indonesian Plumbing Association (APIN) to disseminate this standard and to continue educating manufacturers about the importance of compliance with this new standard to ensure the safety and performance of their products as well as to make their products more competitive at the global market.

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

Implementation of this activity faced 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 made 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 was needed for a higher boost in performance.

The feedback and test results required Ethical Apparel to resource the mask fabric options again and the next round of sampling was delivered in August 2022. Therefore, this pushed the training to October

2022, after which the activity was closed.

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

PY1 – PY4: WHO MedTech Guidance

MDRC 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. 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 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. WHO acknowledged this challenge and has offered to revise by 2024.

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 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 avoids 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, FDA/CDRH, and USAID) consider establishing a dialogue with the WHO to address

these points in bilateral or multilateral fora. The MDRC has also recommended that the GMTA consider a parallel dialogue with the WHO with a view to aligning international aid and capacity building approaches with NRAs.

Activity #16 - Improving Point-of-Care Ultrasound Access (IPOCUSA): Better Maternal Outcomes through Ultrasound Education, Workforce Development, Policy Advocacy and Certification

There are several stakeholders who are advocating and implementing activities to drive the implementation of O-POCUS; it would be more of an advantage to coordinate and align efforts to develop a united and strategic roadmap across organizations and agencies to achieve common goals and prioritize larger impact.

The work to build a training force of those who know how to use O-POCUS as well as how to teach others will take the close collaboration of both university leadership and faculty, as well as those that can adequately train those already in service. It will need to be a multi-faceted approach to train new providers and existing providers, and subsequently evaluate all practitioners in ultrasound to ensure the standard is being met.

Activity #17 – Promoting international standards for Management Systems for UN Sustainable development goals through U.S. leadership

As most of the PC 343 WG 1 meetings are held virtually at times favoring European participants, it has been somewhat difficult for US experts to attend WG 1 meetings. ANSI staff successfully requested that the Chair and Committee Manager of PC 343 rotate the timing of the WG meetings to allow increased participation from experts outside of Europe which has allowed increased participation from US experts in WG 1.

ANSI staff and the US TAG have some concern about the procedural aspects on the development of ISO WD 53001. The PC 343 Committee Leadership have decided to skip the Committee Draft (CD) stage which allows all PC 343 National Bodies to comment on the document. Instead, PC 343 will have an 8-week National Body commenting period. The concern of the TAG is that while the NB commenting period is almost identical to the CD stage, the ISO Directives have no clause describing this commenting period. The ISO Directives does contain a clause on the CD stage and that clause includes the requirement of the PC to respond to each comment submitted. ANSI staff and the US TAG will be closely monitoring the progression of the standard.

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

16	16.1	Kenya	National Nurses Association of Kenya Webinar: Improving Maternal-Fetal Outcomes through access to point of care Ultrasound	May 22nd 2024	300 Nurses 62% Female 38% Male
3	3.3	Ghana, Uganda, Zambia	Webinar Plumbing the Depths: An Analysis of National Quality Infrastructure WASH in Ghana, Uganda, And Zambia.	February 21, 2024	32
15		Côte d'Ivoire	Kick off meeting with USAID Local Mission and DGDDL	2 November 2023	
12	12.5	South Africa	Good Regulatory Practices & Technical Competencies – South African Health Products Regulatory Authority (SAHPRA) & Regulated Sector Workshop	14-16 November 2023	**Day 1**: 234 attendees 180 female, 44 male, 10 did not disclose gender 19 public sector, 215 private sector **Day 2**: 208 attendees 158 female, 40 male, 10 did not disclose gender 21 public sector, 187 private sector **Day 3**: 176 attendees 135 female, 30 male, 11 did not disclose gender 20 public sector, 156 private sector
12	12.5	Kenya	MDRC, KEBS, PPB, and MEDAK – Workshop on Conformity Assessment, Product Imports, and International Standards	10 November 2023	50 attendees 25 female, 21 male, 4 did not disclose gender 18 public sector, 32 private sector
12	12.6	Africa - Regional	MDRC-FDA-AMDF Capacity-building Workshop	6-9 November 2023	**Day 1**: 175 attendees

					87 female, 88 male 74 public sector, 101 private sector **Day 2**: 147 attendees 75 female, 70 male, 2 did not disclose gender 61 public sector, 84 private sector **Day 3**: 141 attendees 75 female, 63 male, 3 did not disclose gender 55 public sector, 86 private sector **Day 4**: 123 attendees 73 female, 48 male, 2 did not disclose gender 43 public sector, 80 private sector
12	12.16	Brazil	MDRC Workshop with INMETRO, ANVISA, NIST, and USFDA	24 October 2023	17 attendees 8 female, 9 male 14 public sector, 3 private sector
12	12.11	Latin America - Regional	MDRC-Inter-American Coalition for Regulatory Convergence in the Medical Technology	12 October 2023	68 attendees 54 female, 14 male 0 public sector, 68 private sector
12	12.16	Latin America - Regional	External Stakeholders Meeting on the Sidelines of the XI PAHO Regional Meeting on the Regulation of Medical Devices	10 October 2023	233 attendees 161 female, 71 male, 1 did not disclose gender 68 public sector, 165 private sector
12	12.16	Mexico	Hybrid GRP Training for MedTech Associations	5 October 2023	121 attendees 84 female, 37 male

					0 public sector, 121 private sector
14	N/A	Mozambique	Standards for Bioethanol Household Energy Workshop	September 18-24, 2023	46 total participants: Private sector: 27 Female participants: 29
12	12.5	Kenya	PPB for Capacity-Building Workshop	22 – 24 August 2023	Day-1 119 attendees 77 female, 42 male (58 private sector) Day-2 96 attendees 58 female, 38 male (26 private sector) Day-3 99 attendees 62 female, 37 male (29 private sector)
5	5.7	West Africa	US Study Tour on Petroleum Harmonization	June 24-29, 2023	Total: 8 (4 private sector, and 3 Women)
12	12.6	Latin America	Webinar on Stability of Medical Devices	1 June 2023	334 attendees 234 female, 96 male, 4 did not declare gender (65 private sector)
12	12.6	Colombia	Training on Processes and Procedures	28 April 2023	51 attendees 32 female, 19 male (0 private sector)
8	8.3	Africa-Zambia	Workshop 3: AWWA Training for water sector utilities, in-person	April 24-25, 2023	22 attendees 8 female, 14 male Government sector

12	12.6	Colombia	Department of the Civil Service (DAFP) and the Superintendency of Industry and Commerce Workshop on citizen participation and the regulatory agenda	21 April, 2023	58 attendees 42 female, 16 male (0 private sector)
12	12.6	Colombia	MoH training on the implementation of GRP	14 April, 2023	81 attendees 57 female, 24 male (0 private sector)
12	12.14	Colombia	Workshop: Small Group Discussion on GRP and QMS	March 24, 2023	42 attendees 26 female, 16 male (5 private sector)
5	5.7	West Africa	Workshop on Petroleum Harmonization	March 20-22, 2023	Total: 28 (8 private sector, and 9 Women)
12	12.10	South East Asia	ASEAN Workshop on Good Regulatory Practices and Medical Device Regulation	February 28, 2023	414 attendees 294 female, 120 male (228 private sector)
1	N/A	ARSO	ARSO Webinars on Bioethanol	February 24, 2023	70 participants
12	12.10	Indonesia	Workshop: Small Group Discussion on GRP and QMS	February 6-7, 2023	42 attendees 26 female, 16 male (5 private sector)
8	8.3	Africa	Workshop 2 on G400 – Utility Management System and G200 – Distribution Systems Operation and Management	January 10, 11, 2023	40 attendees including 12 different private sector organizations present
12	12.05	Africa	Workshop on Good Regulatory Practices and its implementation in the Medical Device Sector in Africa	January 3, 2023	269 attendees 188 female, 81 male (178 private sector)
5	5.7	West Africa	Workshop on harmonization of petroleum standards	December 2022	50 participants
12	12.10	Indonesia	Workshop: Small Group Discussion on GRP and QMS	December 7, 2022	27 attendees 17 female, 10 male

					(5 private sector)
8	8.3	India	Utility Management Standards Training Workshop #4 Final, in-person	December 5-6, 2022	17 participants (6 F/ 11 M)
1	N/A	ARSO	ARSO Webinars on Bioethanol	November 2022	70 participants
12	12.11	LatAm	Workshop for LatAm Project Country Government Representatives	October 26, 2022	13 attendees 7 female, 6 male (0 private sector, all were regulators)
9	9.3	Brazil	NSF/ANSI/CAN Standards 60 training	October 25, 2022	52 participants
5	5.7	West Africa	ARSO Webinar on harmonization of petroleum standards	October 25, 2022	150 participants
12	12.11	LatAm	Coalition Workshop on Self-Testing	October 23, 2022	42 attendees 20 female, 22 male (39 private sector)
9	9.3	Morocco	NSF/ANSI/CAN Standards 60 training	October 20, 2022	21 participants
9	9.3	Morocco	NSF/ANSI/CAN Standards 61 training	October 19, 2022	23 participants
8	8.3	India	Utility Management Standards Training Workshop #3	October 18, 2022	15 participants (4 F/ 11M)
1	N/A	West Africa	Renewable Fuel Workshop hosted by Mali	September 13-14 2022	26 participants
12	12.9	Indonesia	International Medical device Standards and Guidance	8-9 September, 2022	83 attendees 48 female, 35 male (70 private sector)
8	8.3	Africa	Workshop 1 on water utility management standards in Africa	September 7-8, 2022	39 participants (17 government organizations in Lesotho, Malawi, and Zambia)

1	N/A	ARSO	ARSO Webinars on Bioethanol	August/ September 2022	
12	12.16	Mexico	Workshop on Conformity Assessment of MDs and SaMD	29 August, 2022	578 participants 49 in-person, 529 virtual 416 female, 154 male, 8 no declaration (418 private sector)
6	6.2	Africa	Webinar in Africa Concrete and Building Code initiative	August 24, 2022	126 participants
12	12.5	South Africa	Training on GRP Implementation in the Medical Device Sector	10-11 August, 2022	Session 1: 138 attendees 106 female, 28 male, 4 no declaration (119 private sector) Session II: 140 attendees 107 female, 30 male, 3 no declaration (124 private sector)
12	12.9	Indonesia	Training on GRP and Medical Device Regulation	22 July, 2022	62 attendees (45 private sector)
8	8.3	India	Workshop 2 on water utility management standard in India	July, 20-21, 2022	26 participants (all government officials)
5	5.7	West Africa	Workshop on harmonization of petroleum standards	July 2022	27 participants
1	N/A	ARSO	ARSO Webinar on Bioethanol	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,	101 total participants, including representatives

				2022	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 against COVID-19"	31 March, 2022	161 total participants 50 Male/ 108 female/ 3 undeclared 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 Assured and Accessible Diagnostic Tests for Public Health Programs"	6-7 December 2021	Dec 6: 176 participants 108 female, 67 male, 1 undeclared (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	81 participants 66 female, 15 male

				2021	(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	
7	7.1	Indonesia	Technical Committee Meeting 2 (Hybrid)	June 15, 2022	45 (33 Male, 12 Female)
7	7.1	Indonesia	Technical Committee Meeting 1 (Hybrid)	June 10, 2022	6 (4 male, 2 Female)

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.

The success here is also demonstrated by the approval a new activity in Mozambique implemented by Pivot on bio cooking fuel. The implementation began in Year 5 of the SA2 project (see new Activity #14).

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

Through its 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 continued to examine the commonalities and differences in testing across West Africa and developed a deeper understanding of the technical aspects of the ASTM standards. As a result, the participants gained 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, and now have 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 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 SA 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 #8 – Utility Management Standards Training for water sector utilities

In India, AWWA was able to connect with the government Ministry of Housing and Urban Affairs that maintains the overall water and wastewater guidance manual ("Manual of Water Supply & Treatment") followed by India utilities and is now participating with the government to update the guidance manual. This connection was facilitated by USAID's representative in India, R K Srinivasan (Srini). AWWA participation in the update of this important manual will help provide expertise from AWWA for improvements to the manual that will support public health and local economy. Additionally, AWWA will better understand the key drivers of Indian water and wastewater utilities and the India regulatory situation. This insight will be valuable for AWWA member companies that have interests in India water and wastewater activities.

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

The Morocco's Ministry of Health's request for a formal collaboration on the project, their outreach and proposed integration of NSF/ANSI/CAN Standards into the Morocco National Water Committee's discussions certainly contributed to the strong participation as attendance from in-country stakeholders. Not only did the Moroccan MoH provide access to stakeholders, who early in the project were difficult to access, but the MoH collaboration has been instrumental in NSF securing planned continued conversations with these in-country stakeholders on NSF/ANSI Standards and Water Management Planning. Additionally, the MoH's collaboration has been instrumental in NSF being updated on the National Water Committee's conversations and with bringing forward NSF/ANSI resources to the Committee. NSF looks forward to continued engagement with MoH beyond the conclusion of this project.

In Brazil, as a result of the implementation of the NSF/ANSI/CAN Standard 60 project in Brazil, there was promotion of the revision of the technical standard ABNT NBR 15784 with new version targeted to be official in 2024. ABNT NBR 15784: *Produtos químicos utilizados no tratamento de água para consumo humano — Efeitos à saúde — Requisitos* is the Brazilian national standard for evaluating the health effects of water treatment chemicals. ABNT NBR 15784 standard uses NSF 60 and NSF 600 as the technical basis, is the legal basis for chemical products to be used in the treatment of drinking water.

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

Colombia Ministry of Health (MOH) wins national contest on Good Regulatory Practices

During Year 4 under the lead of the MDRC Colombia Liaison, MDRC advanced the formal implementation and institutionalization of GRP requirements at Tiers One and Two. At Tier Two, the Ministry of Health formally approved and published GRP requirements in the form of a regulatory tool updating the Ministry's processes and procedures to ensure compliance with the existing regulatory improvement policy and international TBT requirements for all Ministry regulatory processes. At Tier One, the National Planning

Department (DNP) which is the lead entity to the regulatory policy in Colombia, informed MDRC it would implement those GRP requirements across the whole-of-government.

The approved instrument institutionalizes GRP that must be followed within the Ministry for all regulatory improvement policies, including technical regulations or other administrative acts. The instrument serves as a unique tool that streamlines and bolsters all the stages of the regulatory process, outlining flows charts, tools, regulations, and responsible parties.

The instrument details each stage of this process, including: regulatory agenda; ex-post analysis, complete ex-ante analysis, simple ex-ante analysis, regulations, and public consultation. Moreover, this tool incorporates national and international guidelines, operating in harmony with international regulatory best practices of the OECD and the World Health Organization (WHO). This tool is featured on the MOH website here.

In September 2022, DNP informed MDRC it would implement the MDRC-developed GRP tool across the whole of government. This tool will apply not only to the MOH but all national and local entities in the country – impacting at least 1,300 governmental entities. The tool institutionalizes GRP in Colombia at an unprecedented level. This is a momentous MDRC milestone, significantly improving the project country's NQI, regulatory resilience for future health crises, ability to address any regulatory non-alignments, implement international obligations, and more.

In Q4 2022, as part of the National Planning Department's (DNP) National Contest on Good Regulatory Practices (GRP), the Ministry of Health (MOH) was recognized for its recent formal approval and publication of GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. Recognized by the Contest under the "Institutional Adoption of Good Regulatory Practices" category, the tool was developed under the leadership of MDRC following 9 months of extensive coordination across the Government of Colombia. Those participating government stakeholders included MOH, DNP, Ministry of Commerce, and Public Function Department.

MDRC and USAID Colombia Mission representatives attended and participated in the Contest's award ceremony recognizing MOH on 23 November and this tool was recognized by DNP (Department of National Planning), as the most robust tool nowadays in Colombia.

In Q3 2022, MDRC sent DNP recommendations on priority actions required for full implementation of GRPs to ensure compliance with the whole-of-government obligations. This communication included summaries on existing MDRC workstreams, defined an action plan to develop an institutional architecture to advance GRP, identified the need to designate an entity in charge of guiding the entire government on technical regulation, recommended requiring government actors to implement GRP in all regulations through a gradual mechanism. These recommendations were included in the management transition report for the new government. In addition, MDRC sent recommendations to the Legal Office of the Ministry of Health on the lessons learned, positive aspects and aspects for improvement, based on the progress of the GRP implementation, regarding the questions sent to this address by the team of the new government that was receiving the final report.

Finally, following the approval of the procedure, MDRC conducted additional training activities to formally train MOH officials on the new procedures in the first and second quarter of 2023. These trainings were attended by all areas of the Ministry responsible for regulating including the directorate in charge of regulating medical devices.

WTO Symposium on Technical Barriers to Trade highlights MDRC

In the final week of September 2022, the Coalition operated in its capacity as lead MDRC global implementer of Tier One and Two workstreams by organizing project engagements with the World Trade Organization (WTO) and WHO in Geneva. MDRC team members and partners had the opportunity to engage with key partners, such as PPB, in Geneva through bilateral and multilateral meetings, as well as through panel sessions.

MDRC's increased collaboration with the WTO strengthens its ability to engage on MedTech regulatory convergence efforts. The engagements highlighted the critical role health authorities have in implementing international trade obligations and served to educate critical project partner NRAs.

Additionally, these engagements enabled MDRC to increase global awareness of the importance of compliance with international obligations in resolving technical barriers to trade (TBT), regulatory bottlenecks, and related challenges to the medtech sector – especially in the context of COVID-19. In October, the WTO held its Symposium on Technical Barriers to Trade. There, Deputy United State Representative and Chief of Mission (Geneva) delivered remarks in which they specifically highlighted MDRC, noting the project's important role in not only identifying trade bottlenecks but also addressing them. They highlighted the project's work "conveying assistance to 10 partner countries across Latin America, Africa, and Southeast Asia to increase the transparency and predictability of regulatory systems for medical devices by providing technical assistance on good regulatory practices."

Such recognitions bolster MDRC's capacity building programs, improving patient access to lifesaving medical technology globally.

First Medtech-NRA global level curriculum jointly approved by industry and government

During Year 4, following numerous coordination meetings with FDA regarding capacity building activities for the Africa regional and continental trainings in 2023, FDA signed off on the MD NRA curriculum. The curriculum now constitutes the first ever FDA-industry developed "menu" of MD NRA training options from which to develop training sessions aligned with international reference documents and with an emphasis on GRP and use of standards. With inputs from SAHPRA, PPB, Mecomed, FDA, and MDRC, the training curriculum is also the first Medtech-NRA global level curriculum jointly approved by industry and government.

The training curriculum builds off curricula that were previously developed beginning with the APEC Core Curriculum but also leverages significant inputs from other sources. Additionally, the curriculum incorporates the principles of the WHO GMRF in acknowledging the "stepwise approach" for NRAs to prioritize and regulate within available regulatory resources, focusing, on NRAs ensuring a proper legal foundation for regulations; emphasizing employment of regulatory reliance as a tool and complement to capacities for reviewing domestic dossiers.

The curriculum is meant to serve as a "menu" of options from which specific Africa (and other) training agendas may be compiled. The curriculum is broken into two worksheets:

1. MedTech regulatory fundamentals across a set of core areas;
2. GRP and rulemaking fundamentals.

The curriculum is intended to be introductory, focused on NRA essentials – the absence of which have caused the near totality of global regulatory non-alignments and supply chain bottlenecks. As such, the curriculum does not include more complex subjects such as cybersecurity, AI, SaMD. Rather, the curriculum provides a strong foundation and tis coherent across the policy areas of health, medical

technologies, international reference documents, trade, standards, conformity assessment, proper legal foundations, and foundational good regulatory practices.

The finalization of the curriculum marks a significant MDRC output and will be a GMTA and IMDRF contribution. It is the hope of MDRC that this curriculum will be repurposed and used by other projects seeking to advance global regulatory harmonization and foundational GRP.

COFEPRIS Submits NOM-241 for Revision within the 2024 Regulatory Agenda
Following MDRC's numerous meetings with COFEPRIS and coordination with U.S. government partners as well as the Ministry of Economy (SE) and the Mexican Embassy to the United States, COFEPRIS committed to reviewing NOM-241 and submit corresponding reform within the 2024 regulatory agenda. This commitment marks a significant MDRC outcome in resolving significant trade concerns.

In October 2023, COFEPRIS issued the Strategy for Regulatory Certainty of the Medical Devices Sector which refers to MDRC contributions, the creation of a Committee of GRP as well as the GRP and CA Checklist. Additionally, COFEPRIS confirmed the formal submission of their application to become an affiliate member of MDSAP and commitment to gradually harmonize the national regulation of medical devices with IMDRF, which are major milestones achieved through the joint effort by COFEPRIS, USFDA, and MDRC.

Activity #14 – Standards for Bioethanol Household Energy in Africa (STAND4BE)

The activity established a foundation for the development of a framework that will allow for continued implementation of supporting policies and the expansion of clean fuels. This work directly supports the Economic Stimulus Reforms Package (PAE) Mozambique launched in 2022, including biofuel blending mandates.

Dialogue with policymakers and key private sector companies in 2023 indicated an interest and need for capacity building to create awareness and initiate the implementation of bioethanol fuel standardization activities in Mozambique. The Standards Alliance together with Pivot, held an in-depth 2-day workshop and closed-door meetings to build momentum on the topic and coordinate the next steps for ensuring continued action. Workshop participants included the Mozambican National Institute for Standardization and Quality (INNOQ); Ministry of Mineral Resources and Energy (MIREME); U.S. Dept of Commerce; and GreenLight Africa, a local project development and renewable energy consulting firm, amongst other relevant impacted groups such as clean cooking organizations, women's associations, environmental groups, and other government stakeholders. The 2-day workshop drew over 40 representatives and allowed for information sharing, cross-examination of industry experts, and relationship building.

As a result of this support, the **ASTM E3050** bioethanol cooking and appliance fuel standard was adopted and an additional set of blending standards are expected in 2024. Furthermore, a MOU between Pivot, U.S. Grains Council, and MIREME was signed to allow for continued knowledge sharing, technical assistance, and training over the next three years. The Standards Alliance event provided the means to engage in meaningful dialogue that is now prompting action and providing momentum for Mozambique to develop local agriculture, boost biofuel production and clean stove manufacturing, and establish appropriate standards and policies to support the emerging bioethanol economy.

5. CONTRACTUAL & ADMINISTRATIVE UPDATE

During Year 5, the following updates to sub-awards took place:

- Concluded: CWSC (Activity 3), ASTM (Activity 5), AWWA (Activity 8), MDRC (Activity 12), MSSD (Activity 15)
- Approved/Began Implementation: Inteleos Foundation (Activity 16), NSF International (Activity 18)