Standards Alliance: Phase 2

Quarterly Report

Q1 January 1st- March 31st 2024

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1. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date and End Date:	July 12, 2019 – July 11, 2026
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
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Name of Subcontractors/ Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, ACI, CWSC, IAPMO, Inteleos Foundation
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, West Africa (regional), Ghana, Kenya, Mozambique, South Africa, Indo-Pacific (regional)
Reporting Period:	Q1 January1st- March 31st 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 of the first iteration of the Standards Alliance to support the capacity of developing countries in the areas of legal and regulatory framework, standards development, conformity assessment procedures, and private sector engagement. Achieving these goals also helps companies succeed globally by increasing market access for U.S. companies through more predictable and transparent avenues for trade and investment in partner markets/regions.

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

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

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The first quarter of 2024 continued with the implementation of activities under the approved subawards, and carried out more progress in the development of new activities that will begin implementation under this reporting quarter. In particular, four activities saw more development at the beginning of 2024: work on critical minerals and support for the creation of a US Technical Advisory Group (TAG) to ISO TC 345 on Specialty minerals; support for greater U.S. participation in ISO PC 343 (Management Systems for UN Sustainable development goals); training on sustainable cities in Cote D'Ivoire (CDI); and support around medical devices for ultrasound care in Kenya. ANSI also sent a proposed subaward for a new activity in Senegal around Bottled Water standards to USAID for approval, and outreach continued for future work in the automotive sector in Brazil, and digital infrastructure in Tanzania.

Finally, during this reporting period the CWSC concluded its activities with the release of the Trend Report entitled "Plumbing the Depths: An Analysis of NQI WASH in Ghana, Uganda, and Zambia," and virtual webinar which celebrated the report to bring together stakeholders from target countries to discuss its findings.

2.2 Non-COVID-19 Related Activities Activity

Implementation Progress

GLOBAL

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

Activity #13 – Support for critical minerals standardization coordination (new addition to work plan in Q3 2023)

In March 2023, ISO/TMB and 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.*

ANSI, as the U.S. representative to ISO and an active member of ISO/TMB and ISO Council, participated in the SAG. The SAG on Critical Minerals recently provided a report of its recommendations to the ISO/TMB, and in parallel, a new technical committee was established, ISO TC 345 on Specialty Metals and Minerals. In Year 5, the SA2 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.

Implementation continued during Q1 2024, where ANSI managed a U.S. TAG to participate 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;

- Under Q2, the project leads will set up a meeting once a month between ANSI and USAID to share period updates on the evolution of the activity.

Activity #17 – Promoting international standards for Management Systems for UN Sustainable development goals through U.S. leadership (new addition to work plan in Q1 2024)

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 eg. 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, during this first quarter of 2024, the primary activity was formation and administration of a U.S. TAG for ISO PC 343. This is to enable U.S. contributions toward its international outputs; and work with U.S. government agencies and private sector to align future work within ISO with U.S. policies and positions.

During this reporting quarter ANSI and USAID organized a first meeting with key government stakeholders – such as the EPA, GPO, and NIST – where it introduced both the Standards Alliance program and also provided a training on ISO 9000, which is an international management system standard for quality management. After this first meeting the team submitted application for accreditation of the US TAG for PC 343 in February 2024. Since this activity is being implemented in close cooperation with USAID, M. Daniel Vasquez, A.O.R for the Standards Alliance Phase 2 program has been selected as the chair of the US TAG.

The first US TAG meeting was held virtually on February 2 from 2:30 pm to 4:00 pm ET. On that call, we agreed to approve the current ISO deliverable that members are reviewing, ISO DPAS 53002, Guidelines for contributing to the United Nations Sustainable Development Goals, with comments. The ballot passed successfully and the document will proceed to publication. All technical comments received will be addressed during the next iteration of the document.

A virtual meeting was held on February 26 for relevant U.S. stakeholders to discuss the importance of joining the US TAG to support U.S. national consensus-based participation in ISO/PC 343. During this meeting, ANSI staff presented information on the ISO and ANSI organizational structure and role, U.S. TAG Functions and Responsibilities, and how interested experts can join the US TAG to ISO/PC 343. This call helped to publicize the PC 343 activity and increase the TAG membership.

ANSI has published various news articles and utilized social media to recruit TAG members. A website was created for the US TAG to PC 343 which contains a repository of PC 343 documents and all emails sent to TAG membership which can be found here.

The next virtual PC 343/WG 1 meeting is scheduled for May 26 through May 27. In preparation for the WG 1 meeting, the convenor has requested that WG 1 experts submit their input on ISO/WD 53001 in the ISO balloting portal by May 17. A virtual TAG meeting will be convened on May 6th to assist the U.S. WG 1 experts prepare for the upcoming meeting.

AFRICA

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

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

Partner countries: Ghana, Uganda, and Zambia

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

This quarter, 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.

Further, 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.

This project is now complete.

Activity #14 – Standards for Bioethanol Household Energy in Africa (STAND4BE) *(new addition to work plan in Q3 2023)*

Partner country: Mozambique

In 2023, the team organized a two-day capacity-building training in Maputo, 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 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). It was very timely as it allowed the program to pursue ways of implementing the biofuels strategy in synergy with other efforts undertaken by the U.S. Government. Pivot had been leading policy discussions with a group of stakeholders over the last year prior to this work, which allowed the Standards Alliance to structure the event with a greater awareness of dynamics in the country, and make connections that were beneficial to workshop implementation.

This activity aimed at creating a clear pathway for the adoption of ASTM E3050 following an in-depth technical working session in which INNOQ participated. The process of adoption was undertaken by INNOQ, and they successfully adopted the standard in December 2023.

During the post implementation of the project the team has been working to achieve other milestones that were discussed during the training such as the adoption of 3-4 additional relevant biofuel standards through ASTM. During Q1 2024 INNOQ has been in the process of vetting existing standards that they could adopt for Mozambique and anticipates possible adoption during Q2 2024.

Finally, Pivot is also following 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 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 the next step is to host an official signing of the MoU in Mozambique.

Activity #15 – Supporting localization through the implementation of ISO 37101: Sustainable Development in Communities — Management System for Sustainable Development (MSSD) *(new addition to work plan in Q4 2023)*

Partner country: Côte d'Ivoire

In Q1 the project consultants worked to develop two separate agendas for the first two events – government policy roundtable #1 and pilot community workshop #1, including recruiting government and private sector speakers and developing PPT presentations. They also worked in consultation with ANSI to coordinate the various logistics for delivering these hybrid events, including locating interpretation services, scheduling rehearsal calls with speakers, and other related activities to ensure smooth delivery.

The project team ran into significant hurdles with key public sector partners in the lead-up to the workshop and roundtable event days. The first issue was their insistence on discussing issues regarding

logistical expenses and additional attendees beyond the agreed scope of work. These discussions took up a significant amount of planning time during team check-in/update calls, which were intended to focus on more substantive issues i.e., agenda content. They were particularly interested in getting the Standards Alliance to pay for unbudgeted expenses including media advertising, workshop banners, pens, writing pads, as well as two square meals for a 3-hour hybrid event, amongst other items. Additionally, two planned events were cancelled on two separate occasions. The first cancellation was related to an unexpected health situation and the other was related to the meeting space being obligated for a separate activity. The project consultants are now working to reschedule the workshop and policy roundtable to take place in May – based on the availability of U.S. speakers, the meeting location and interpretation services.

Activity #16 - Improving Point-of-Care Ultrasound Access (IPOCUSA): Better Maternal Outcomes through Ultrasound Education, Workforce Development, Policy Advocacy and Certification *(new addition to work plan in Q1 2024)*

Maternal Health Summits convened in November 2022 and September 2023 themed: 'Improving Maternal-Fetal Outcomes Through Access to Ultrasound: Education, Training, Assessment and Continued Proficiency for Midwives and Nurses," have been catalytic to addressing the Ministry of Health's reproductive health strategy that highlights the need for innovative approaches to address SDG 3 targets and indicators: reducing maternal mortality. The meetings brought together thought leaders and key stakeholders to hold a discussion on the current maternal and fetal health care state and the impact of introduction of Point of Care Ultrasound. Point-of-care ultrasound (POCUS) serves as a valuable tool for identifying obstetric risk factors, complications, and emergencies related to the maternal, fetal, placental, and umbilical cord aspects of pregnancy. By facilitating early intervention and timely referrals to appropriate obstetric care, POCUS offers expectant mothers and their unborn babies a fighting chance, thereby contributing to the reduction of avoidable deaths and complications. In Kenya, several initiatives have been launched to equip non-traditional medical imaging healthcare professionals, such as nurses, midwives, clinical officers, and general practitioners, with compact ultrasound devices. These devices are designed to detect potential obstetric issues in healthcare settings lacking trained sonographers and radiologists. Advancements in ultrasound technology, rechargeable batteries, and system design have led to the development of increasingly innovative products that are more portable, provide better image resolution, and are easier to use for non-imaging healthcare workers. The forums discussions aimed at creating an enabling environment in the development of a unified roadmap to strengthen skills of various health cadres through implementation of ultrasound education, training, and certification as a focused strategy to reducing maternal-fetal morbidity and mortality in Kenya.

At our initial stakeholder convenings in Kenya, it was a unanimous agreement that there is need for point of care ultrasound in the primary health care setting. However, a few areas require more input. These are:

- Policy, legal and regulatory reforms, and frameworks
- Standardization of training (who will do the training, what are entry requirements for the training, how should the training be conducted, how long should the training be).
- Operational deployment of POCUS - the scope of practice and standardization in ultrasonography reporting.
- Healthcare financing for POCUS

In January 2024, the formation of multidisciplinary cross-cadres technical working groups that incorporates both private and public sectors, supported by the Ministry of Health to assist in development of policy guidelines. Inteleos was invited to participate as a member of the obstetrical point of care steering committee with the inception meeting hosted on February 8th, 2024, with the theme of development of policy guidelines by June 2024. On 27th March 2024, working group was convened to forge a roadmap for curriculum and training; Inteleos has been invited to be a part of the POCUS curriculum development group and will be working alongside the lead consultant from the University of Nairobi.

Inteleos is in the process of finalizing a landscape/baseline study, supporting the Ministry of Health with an objective needs assessment to guide implementation-training, certification, and equipment supply.

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

Partner country: Senegal

The Senegalese standardization body, Association Sénégalaise de Normalisation (ASN), requested Standards Alliance: Phase 2 support in the development of a Bottled Water Certification scheme according to the West Africa Standard ECOSTAND 022, which Senegal has adopted. NSF International was approached due its experience in this sector. NSF's Bottled Water Certification program is the only accredited product certification program that offers analysis for bottled water, including microbiological, chemical, and radiological analyses in accordance with national and international regulations, such as FDA, EPA, EU, ANVISA, BIS and China Natural Mineral Water. Additionally, NSF has a Registration available for the manufacturing process. The project will include both a product certification with an analytical component and support and training for auditing and Good Manufacturing (GMP) practices.

ANSI submitted the request for funding through a subaward to NSF International to USAID on February 28, 2024.

USAID approved the project April 2, 2024. Contract finalization is underway between ANSI and NSF.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

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

Currently, IAPMO is focused on the implementation of the SNI 122:2022 standard which includes making it mandatory by the Ministry of Industry. IAPMO is working with industry to encourage the Ministry to take action. To date, the Ministry has not taken action to make this standard mandatory. IAPMO continues to conduct knowledge sharing about product safety and testing methods to manufacturers and to raise awareness about public health and safety benefits to the user. IAPMO will be meeting with APIN

(Indonesia's Plumbing Manufacturers Association) in Q2 to discuss further outreach and implementation of the standard.

Following the achievement of PT IAPMO Group's faucet testing laboratory to conduct tests to SNI 122:2022 (achieved in Q2 2023), the lab's accreditation by KAN is still pending. Final paperwork was submitted to KAN in Q4 2023. IAPMO's lab is now waiting for its scope expansion assessment by KAN. Based on conversations with KAN, IAPMO still anticipates that the audit will take place by Q2 with official accreditation and recognition following shortly thereafter by Q3 2024.

IAPMO continues to collaborate the Indonesian Plumbing Association (APIN) on the implementation of SNI 122:2022. Last quarter, 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.

2.3 COVID-19 Related Activities Implementation Progress

GLOBAL

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

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

Global

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

Although substantive training was completed in 2023, in Q1 2024, MDRC continued to advance GRP in medical technology regulatory frameworks through engagements at local, regional, and global levels. The team ensured outstanding action items were completed and necessary handovers were performed to ensure sustainable project impact. The final project report is currently under development, with ANSI expected to provide feedback on the draft during May and a final version would be shared with USAID before the end of implementation, which falls at the end of the following quarter.

Africa

Activity #12.6 – Tier One and Two Regional Meetings/Trainings

Regional

In Q1, MDRC continued to close out and finalize activities related to 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 below, with additional information in the November monthly report and the MDRC website.

Ghana

In Q4, MDRC sponsored five Ghana FDA officials to attend the MDRC-FDA-AMDF capacity building workshop on 6-9 November and facilitated in-person interactions that lead to a follow up session mainly focused on implementation of GRPs where the GRP and CA checklists were shared to facilitate the process. MDRC additionally held a formal meeting with Ghana FDA whose representatives highlighted ISO 13485 as a top priority and requested additional training. MDRC also identified reliance – specifically the need to develop specific guidance for implementation – as a priority area. MDRC mentioned raised the importance of GRP implementation and offered to analyze Ghana FDA's current policy for comparison with GRP alignment and proposed several dates in January to regroup. MDRC continued to follow up on this work where relevant in Q1 to ensure continued program support and final tentative updates will be shared in the final report of the MDRC activity.

Kenya

During Q4, MDRC continued the momentum from capacity building activities with PPB in August 2023 and led PPB through a review of their regulatory instrument development processes. MDRC provided three critical documents to assist the review:

- Report containing recommendations and a gap analysis on the current guidelines for regulatory process and the Standard Operating Procedure (SOP) on public consultation
- MDRC-annotated guideline for regulatory process, and a compliance checklist that considers the TBT agreement
- African Continental Free Trade Area (AfCFTA) requirements

MDRC committed to remain available, offering further discussion or clarification.

On 10 November, MDRC, KEBS, PPB and MEDAK conducted the Workshop on "Conformity Assessment, Product Imports & International Standards for discussions on Conformity Assessment Process for Medical Devices in Kenya", the "Role of PPB concerning PVoC", and the "Role of National and regional Standards Development Organizations and the IECEE CB Scheme". The workshop concluded with closing remarks from MDRC, USAID, KEBS, MEDAK, and PPB, solidifying the collaborative commitment to advancing medical device standards and conformity assessment. Throughout Q1, MDRC continued to engage with stakeholders where relevant to provide additional support and engagement following the workshop.

MDRC also continued its engagement with MEDAK in Q1, specifically regarding the Pre-Export Verification of Conformity to Standard (PVoC) in advance of the workshop. MDRC regularly emphasized the importance of case studies to support the elimination of duplicative, redundant and overly restrictive requirements established through PVoC for medical devices.

South Africa

Following extensive planning, MDRC held a capacity building workshop with SAHPRA on 14-16 November. MDRC provided additional support to stakeholders, including SAHPRA following the event into Q1.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

Indonesia:

During Q4, MDRC submitted the Bahasa translations of the three MDRC deliverables to the Indonesian Ministry of Health (MoH): GRP recommendations for the MoH's SOP on medical device regulation; Guidance on implementation of GRP and the TBT/CA checklists; and GRP recommendations for implementation of the medtech-relevant articles of the Omnibus Health Law. In Q1, MDRC continued to incorporate feedback and provide additional support as needed.

Latin America

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

The Coalition led regional and local project efforts throughout Q4 2023 and continued to provide post event support in Q1 as needed. An overview meetings and trainings may be found in the MDRC quarterly report and Section 3 Stakeholder Participation and Involvement.

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

In Q1, MDRC provided additional support and performed project close out activities on several additional projects from previous quarters. During Q4, MDRC worked in close coordination with the U.S. FDA Latin America office to plan a workshop deepening understanding and implementation of GRPs, with a focus on public consultations and regulatory impact effectiveness. The program also included the participation of MDRC and the Latin American Federation of the Pharmaceutical Industry (FIFARMA), which presented an opportunity for both entities to outline their activities and intended impacts to avoid duplicative work.

This series of engagements allowed MDRC to advance objectives in the region and deepen relations with project partners. Notably, for the first time under SA2, COFEPRIS participated in person, presenting on EUA during the External Stakeholders Session.

Brazil

During Q4, MDRC concluded workstreams with key stakeholders including ANVISA, MDIC, and INMETRO focused on regulatory cooperation and international agreements and likewise provided additional support as needed in Q1.

In Q3 2023, Brazil's engagement in the August PPB trainings highlighted the project country's active involvement in international agreements, collaborative regulatory efforts, and capacity building initiatives pertaining to medical devices. ANVISA's engagement with international partners in Q4 further emphasized Brazil's role in advancing regulatory practices at the regional and global level.

Finally, following Q3 2023 meetings with ANVISA to review the WHO/TBT Agreement and the U.S.-Brazil ATEC Protocol which addressed the potential negotiation of a sectorial annex on medical devices

between Brazil and the United States, AdvaMed suggested to the USFDA and ANVISA that they consider the establishment of an enhanced USFDA-ANVISA medical device regulatory cooperation agreement, incorporating the recommendations of the MDRC, that could later be formalized by the respective trade authorities into a U.S.-Brazil ATEC medical device annex, building and expanding upon the USMCA.

Colombia

In Q1, under the direction of workplans developed during Q3, MDRC continued to build upon the substantial advancements in its collaborative efforts with local Colombian stakeholders to enhance regulatory practices, promote international alignment, and foster collaboration with government entities to streamline processes and achieve a stronger regulatory environment made in Q4. Key stakeholders and work advanced include:

- **Ministry of Commerce, Industry and Tourism (MinCIT)**: MDRC collaborated with MinCIT on final project initiatives, including designing guidelines for the identification of technical regulations based on the application of the term "administrative requests" included in the definition of technical regulation that is part of the TBT Agreement. Simultaneously, MDRC supported the development of a comprehensive checklist for the TBT/CA. Both are cross-cutting tools available to all entities developing technical regulations at the national level.

  MDRC presented the checklist and a guideline to align interpretation criteria of technical regulations under their current regulatory framework. The checklist and guideline were approved as foundational resources in November and December.

  Additionally, efforts were made in conjunction with the National Planning Department (DNP) to incorporate the guide and checklist into the procedure developed by the DNP for the implementation of public regulatory policy, which is part of the Integrated Planning and Management Model (MIPG) applicable to national and municipal government entities. By December, both were officially included on the MIPG.

- **Ministry of Health (MoH)**: MDRC collaborated with the Ministry of Health (MoH) to successfully include an enhanced version of the checklist in the approved procedure. Enhancements are related to additional activity details to specifying stages such as regulatory agenda setting, ex-ante analysis, ex-post analysis, and public participation processes. At the end of December 2023, the Ministry approved and incorporated the checklist into the regulatory procedure, which includes technical regulations on medical devices and is applicable to the entire Ministry.

  Additionally, MDRC participated in a problem tree presentation by MoH on the ex-ante analysis of decrees 4527 and 3770. This problem tree, developed collaboratively with MDRC in the Q1 2023, was reaffirmed as relevant, emphasizing the ongoing importance of implementing reliance and aligning with international standards.

- **National Planning Department (DNP)**: Utilizing the GRP procedure adopted by the Ministry of Health, MDRC collaborated with the National Planning Department (DNP) to further refine a proposed procedure aimed at implementing the Regulatory Improvement Policy across all national government entities. In December 2023, DNP incorporated this procedure into the Integrated Planning and Management Model (MIPG) for adoption by national and local entities, starting in the Q1 2024, which will be supported by the procedural toolkit developed by MDRC. Finally, interactions with Colombia's single public consultation system (SUCOP) led to the development of a format accepted by the DNP to promote and analyze stakeholder participation, which will be made available to all national and municipal government entities.

Finally, MDRC engaged with the National Business Association of Colombia (ANDI), Medical Devices Chamber to provide a project update and overview workstreams with MinCIT, MoH, and DNP in regards to GRP implementation and interpretation criteria linking international and domestic obligations.

Mexico

In Q1, MDRC continued to support the significant progress it made in Q4 in its engagement with COFEPRIS. Most noteworthy was the achievement, on 31 October, 2023 when COFEPRIS submitted NOM-241 to the Ministry of Economy for inclusion for revision within the 2024 National Quality Infrastructure Plan.

In discussions with COFEPRIS, plans were confirmed for representatives' participation in the MDRC External Stakeholders' session, where expectations for MDSAP application approval were shared. During these discussions, COFEPRIS mentioned challenges in ISO 13485 recognition, prompting MDRC to offer technical support, while the status of an equivalence agreement consultation awaits legal department advice. COFEPRIS also shared the plans for multi-stakeholder working groups to draft updates on NOM-137 (labeling) and NOM-240 (Post-market Surveillance). These workstreams have advanced quickly, and the first drafts were completed in November. The updates will be published for open public consultation in 2023-2024, and the working groups expected that TBT will be notified of these drafts for international consultation. It was agreed that the additional training session on stability studies would be held in 2024 at a date to be further determined.

Peru

In Q1, MDRC continued to actively engage the newly appointed director of DIGEMID and the private sector represented by CCL COMSALUD and the Medical Device Committee of AMCHAM-ALAFARPE (CDMMAA), providing visibility of an intention to revamp the Peruvian regulatory framework for medical devices.

2.4 Implementation Challenges

Activity #7 – Increase the Flow of WASH Services

Work on the Risk Impact Analysis (RIA), 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 to certify their relevant products to the new standard who are reluctant to do so without the standard being made mandatory. IAPMO is working closely a domestic faucet manufacturer in Indonesia to prepare their product to meet the requirements of SNI 122 in advance of testing and certification to the new standard.

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

As a result of scheduling conflicts with Ivorian stakeholders there were significant delays in executing the information sharing roundtable event and as a result, similar delays have affected the half-day workshop

on ISO 37120. While previously anticipated in Q1, the events are now expected in May 2024. Complicating efforts, US companies, FCS and American Chamber of Commerce in CDI are not responding to repeated requests to engage as well.

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

In education and curricula development, there is some domestic apprehension that skill expansion, defining scopes of practice, and adopting best practice that have been implemented successfully in other regions may be difficult in country. Additionally, it has been identified that academic faculty may lack the necessary skills to train stakeholders in these areas. As such, a major priority will be investing in faculty competency and proficiency in POCUS to be able to scale efforts in in-service training.

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

As most of the PC 343 WG1 meetings are held virtually at times favoring European participants, it has been somewhat difficult for US experts to attend WG1 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.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
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
16	1	Kenya	Project Lead Team- Planning Session	March 11, 2024	Country Coordinator, Project Lead, Project Administrator, Support Staff
16	1	Kenya	Project Lead Team- Planning Session	March 25, 2024	Country Coordinator, Project Lead, Project Administrator, Support Staff

4. RESULTS ACHIEVED

Performance Indicator #2: Number of trainings conducted about the value of using their national quality infrastructure

Under this reporting period for this performance indicator there are a total of **0** trainings targeted, but 1 training did occur as listed below. A breakdown of the different workshops is presented by activity.[1]

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

CWSC anticipated 1 workshop in Q4 2023. This target was not met as CWSC noted in early Q4 2023 that the December-January holiday/festive period in the target countries conflicted with their workshop dates. Therefore, the dates were moved to accommodate the local holiday schedules and to maximize participation in Q1 2024. The CWSC's target of 1 workshop has been met.

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

For Activity 16, there were no expected Performance Indicators in Q1 due to the short duration of the reporting period, as the subaward was finalized mid-quarter. There is one training and advocacy engagement anticipated for Q2 2024.

5. LESSONS LEARNED

Activity #7 – Increase the Flow of WASH Services

Domestic manufacturers are hesitant about supporting a mandatory standard for faucets. IAPMO is working to educate these manufacturers about the role of this new standard in ensuring the safety and performance of their products as well in making their products more competitive in the global market. The new costs of testing and certification processes which have never been incurred before by these manufacturers continue to be a barrier. Domestic faucet manufacturers are now expressing their concern that they need to improve their products to meet the requirements of SNI 122.

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

The project team continued to incorporate lessons learned on hybrid in-person/virtual engagements with stakeholders. Scheduling MDRC programming in conjunction with other major events and multilateral forums per requests from the FDA and MDRC NRAs has significantly facilitated MDRC advancement.

[1] Activities not mentioned under this section did not select it for their implementation or are no longer under implementation.

The project team continues to utilize its online capacity-building and digital resource capabilities to extend programming to a large virtual audience. While in-person training is extremely effective, most participants of MDRC trainings remain virtual. MDRC's virtual platform and Zoom licenses are critical to reaching those participants and offering simultaneous language interpretation for both in-person and virtual attendees. These learnings are increasingly critical in the effective execution of capacity building. Identifying the appropriate possible balance between theorical, hand-on trainings and open dialogue guided sessions is critical while planning future capacity building events, to maximize learning opportunities.

Throughout the course of the project, the MDRC has made the majority of its training sessions public, both real time as well as making the video and audio recordings publicly available (in various MDRC country languages) together with event agendas and presentations, as an enduring information resource. This has served three primary functions: (1) it has provided increased "shelf life" to MDRC trainings that include the limited time of global subject matter experts, accommodating audience schedules, particularly important for LMIC NRAs and industry; (2) it has provided transparency to MDRC-provided technical assistance, allowing partner authorities such as the USFDA, USTR, WHO, WTO et al to be aware of the content that MDRC is advancing and providing them an opportunity to provide feedback; (3) it has provided transparency to MDRC-provided technical assistance, allowing other USAID and USTDA divisions and project teams, in many cases working with the same partner country authorities, to be aware of the content that MDRC is advancing with a view to maximizing coordination of USG-funded TA to partner countries. The MDRC recommends considerations of these lessons learned as a benchmark for similar capacity building projects with medical device NRAs and industry.

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

As a result of the unfortunate delays throughout Q1, the team recognizes that in-country stakeholders may need more lead time to ensure proper alignment and preparation before events.

While USAID HQ continues to be very supportive and USAID CDI Mission has also offered help on a recent call, private-sector US stakeholders remain difficult to engage and may require additional lead time and different techniques in the future.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity#	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
16	1	Kenya	MOH-Curriculum Development Meeting	April 23, 2024	Kenya	TBD	
16	1	Kenya	Private Sector Training of Nurse Midwives	May 2024	Kenya	Will update in the monthly	

						meeting with the Mission	
17		Virtual		ISO/PC 343/WG 1 "Development of ISO 53001" 4th WG1 Meeting	May 26, 2024	Virtual	