



Standards Alliance: Phase 2

Quarterly Report

Q2 April 1st - June 30th 2024

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I. PROGRAM OVERVIEW/SUMMARY

Program Name:	Standards Alliance: Phase 2
Activity Start Date and End Date:	July 12, 2019 – July 11, 2026
Name of Prime Implementing Partner:	American National Standards Institute (ANSI)
Agreement Number:	#7200AA19CA00012
Name of Subcontractors/ Subawardees:	Ethical Apparel Africa, AdvaMed, ASTM International, NSF, AWWA, 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:	Q2 April 1 st - June 30 th 2024

I.1 Program Description/Introduction

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

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

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

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

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The second quarter of 2024 continued with the implementation of activities under the approved subawards, and saw the full start of the implementation phase for three activities in particular. These were focused 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); and support around medical devices for ultrasound care in Kenya. ANSI also received concurrence for a new subaward to start implementation for an activity around Water Sanitation and Bottle Certification in Senegal. In addition to the launch of these new activities, the team also began the post implementation and reporting phase of its largest activity under the SA2 program, and plans to share a final report for the Medical Devices and Regulatory Convergence activity during Q3 of 2024.

Finally, during this reporting period the activity around sustainable cities in Cote d'Ivoire was closed with available remaining funds redirected to potential new activities around the automotive sector and/or digital infrastructure.

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

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 Q2 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;
- 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

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 U.S. government agencies and private sector to align future work within ISO with U.S. policies and positions.

During this reporting quarter the ANSI team held a second virtual PC 343 US TAG meeting in May 2024. The purpose of the meeting was to discuss the TAG member comments on ISO WD 53001.3. The TAG Chair facilitated the discussion of TAG members and as a result, comments from 7 TAG members were submitted to PC 343/WG I for consideration. PC 343/WG I is expected to circulate an updated Working Draft in September.

This builds on meetings held with USAID, EPA, GPO and NIST during Q1, as well as the approval of ISO DPAS 53002 and guidelines for contributing to the United Nations Sustainable Development Goals, with comments.

ANSI has published various news articles and utilized social media to recruit TAG members. 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 this quarter, 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 MOU does have some concerning language, Mr. Cornish reported that he will encourage the ANSI President, Joe Bhatia, to vote to approve the MOU at the September 2024 ISO Council meeting in Colombia. ISO plans to have a training session on the MOU and its implementation with PC 343 members later this summer.

AFRICA

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

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

Partner country: Mozambique

Implementing partner: Pivot

Although this activity completed in 2023, the partners report on follow-on outcomes the project continued to work to achieve other milestones; such as the adoption of 3-4 additional relevant biofuel standards through ASTM. During Q2 2024 INNOQ continued the process of vetting existing standards for adoption by Mozambique.

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.

After those outcomes were achieved the team has shared a final report with USAID in April 2024; and it has also started to engage with other stakeholders in the region that have express interest in adopting ASTM E3050 should new funds be made available for this project.

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

Partner country: Côte d'Ivoire = **Project closed**

In Q2 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. These trainings should have taken place in May 2024 but were unable to go forward after challenging coordination efforts, also encountered during Q1 of 2024, with the local government stakeholder in the country.

Based on these 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, 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

Implementing Partner: The Inteleos Foundation

During this quarter the team has been developing a training rooted in the Kenya National Reproductive Health Policy (2022-2032), which envisions the highest reproductive health status for all Kenyans. By implementing this curriculum, the Kenya Ministry of Health (MOH) aligns with the country's broader developmental aspirations, including Vision 2030, UN-SDG 3 and Universal Health Coverage (UHC). Additionally, MOH aims to equip healthcare professionals with innovative solutions grounded in empirical evidence for quality of maternal healthcare.

Ultimately, the goal of this curriculum and certification is 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 standard 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, 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.

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, Inteleos has 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 (new addition to work plan in Q2 2024)

Partner country: Senegal

Implementing Partner: NSF International

NSF began the Bottled Water + project on May 13, 2024. NSF conducted internal kick-off meetings with the three program areas involved in the project Beverage Quality/Food, Laboratory, Food Sustainability Advisory Solutions and, externally, with the ANSI and ASN. These meetings provided introductions and outlined next steps for the project.

The project is currently contracted for virtual training only. Potential funding for in-person training was identified and a budget for the inclusion of in-person training was requested by USAID. A revised proposal and budget reflecting the additional budget for in-person training has been submitted to USAID.

Activity #1 - ISO 17065 Needs assessment/baseline – gap analysis

To inform the ISO 17065 Needs Assessment/Baseline Gap Analysis, ASN shared all documentation related to their current ISO 17065 accreditation and ECOSTAND 022 program. This included information on current document storage practices and resources, ISO 17065 accreditation administrator and scope, all internal and external forms, training documents, Standard Operating Procedures (SOPs), lab documents, information on document storage.

NSF's Beverage Quality/Food team completed an initial inventory and review of the documents. The review of these initial documents was found to be very encouraging as there already much in place and solid foundation from which to start. It was noted that the internal Quality Manual and L-029 will be particularly helpful in terms of assessing what ASN is already established and what is still needed (gap). With the initial document transfer, three (3) documents were provided in French (DS 1 decret 2002-746 du 19 juillet 2002; DS 2 Recepisse de declaration d'association; and DS 3 Statut ASN) and was request was made back to ASN if English versions can be made available. NSF's Beverage Quality/Food team will also begin an in-depth ISO 17065 gap analysis and process mapping.

Activity #2 - ECOSTAND 022 review by NSF Laboratories, Auditing Staff and Standards team

NSF's Beverage Quality and Laboratory team members initiated a review of ECOSTAND 022 (in English). Beverage Quality/Food has asked ASN if they are able to provide a list of documents referenced in in

ECOSTAND. These are: ECOSTAND 17; ECOSTAND 46; ECOSTAND 50; ECOSTAND 52; and CAC/GL 50.

NSF Laboratories has identified the list of methods referenced in ECOSTAND 022, which are:

Parameter	Method Referenced
Color	ISO 7887
Odor	EN1622
Flavour/Taste	EN1622
Turbidity	ISO7027
Metals	ISO 17578-1 or -2
Metals	ISO 11885 or 17294-2
Metals	ISO 6333 or 15923-2
Metals	ISO 17379-1
Metals	ISO 9390
Metals	ISO 5961 or 8288
Metals	ISO 9174
Cyanide	ISO 14403-1 or 2 or 6703-1

NSF's Laboratory team will be purchasing the identified methods and begin their review. All options for those method that indicate "or" will be purchased in effort to identify opportunities for optimization.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

Implementing Partner: IAPMO

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

IAPMO continues to work on knowledge sharing about product safety and testing methods to manufacturers and to raise awareness about public health and safety benefits to the user. IAPMO met with APIN (Indonesia's Plumbing Manufacturers Association) in Q2 to discuss implementation of the standard. IAPMO discussed with APIN and their members the need to address lead leaching in their products, including faucets, and the importance of the SNI in ensuring quality infrastructure particularly in light of the development of the new capital city in Indonesia.

IAPMO also entered into discussions with the Indonesia distributor of Moen products to use the SNI certification of plumbing products, including faucets, in their marketing efforts.

IAPMO's testing lab completed their accreditation audit with KAN for SNI 122 in May 2024 and the official accreditation audit is expected in Q3. IAPMO's certification program for SNI 122 is scheduled to be audited by KAN in July 2024. The official accreditation is expected by the beginning of Q4 2024.

In Q2, IAPMO signed an MOU with RUCIKA Institute which is training arm of the leading manufacturer of plastic piping in Indonesia to collaborate in certifying plumbing personnel. This training will provide hands-on skills development and exposure to Indonesia's requirements and SNI's related to plumbing. IAPMO is currently working with RUCIKA Institute to finalize the course curriculum and to identify trainers with training expected to launch in Q1 2025.

A no-cost extension was approved for IAPMO on June 28, 2024, extending the project to April 11, 2026.

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
Implementing partner: AdvaMed

Although all the substantive trainings were completed in 2023, in Q2 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 will be shared in Q3 2024, as the close of this current reporting quarter marks the end of the implementation phase of this activity.

Africa

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

Regional

Africa

In Q2, 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.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

During Q4 2023, 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 Q2 2024, 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 Q2 2024 as needed.

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

In Q2, MDRC continued to provide additional support and performed project close out activities on several additional projects from previous quarters.

Colombia

In Q2 2024, under the direction of workplans developed during Q3 2023, 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 2023. 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 Q2 2024, MDRC continued to support the significant progress it made in Q4 2023 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 Q2 2024, 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

As previously reported, work on the 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 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 with most of these discussions ongoing.

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 I meetings are held virtually at times favoring European participants, it has been somewhat difficult for US experts to attend WG I 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 I.

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. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
16		Kenya	National Nurses Association of Kenya Webinar: Improving Maternal-Fetal Outcomes through access to point of care Ultrasound	May 22 nd 2024	300 Nurses 62% Female 38% Male

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 1 training targeted and met. A breakdown is presented by activity.¹

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 was one webinar offered during Q2, which aligns with the targeted number. There is one training and advocacy engagement anticipated for Q3 2024.

5. LESSONS LEARNED

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 and need to close the activity in Q2 2024, the team recognizes a stronger alignment from the project design phase is needed for the ability to carry on activities with the

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

local stakeholders. The team will work in the future to seek better alignment with local government entities so that implementation may be facilitated and carried out.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity#	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
13		Global		ISO/TC 345 Meeting	Sept 2024	Virtual	TBD
16		Kenya		Medic East Africa	Sept 2024	Nairobi Kenya	TBD