



Standards Alliance: Phase 2

Quarterly Report

Q3 July 1st - September 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, The 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:	Q3 July 1 st - September 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 third quarter of 2024 continued with the implementation of activities under the approved work plan and subawards. 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, as well as work around Bottled Water certification in Senegal. In addition to the continuation of these activities, the team concluded the post implementation and reporting phase of its largest activity under the SA2 program, and has shared a final report for the Medical Devices and Regulatory Convergence activity during Q3 of 2024.

Finally, during this reporting period the activity the SA2 program completed two modifications to the Agreement with USAID, adding funding for the implementation of new activities until 2026. To support programming of these funds, ANSI and USAID shared a call for proposals with local stakeholders via USAID missions in Africa, as well as began discussions to expand existing areas of work. The team is reviewing concept notes received from stakeholders in Kenya and Tanzania, and if approved expects implementation to start during Q4 2024. The second and largest source of funding, including \$1.5 million USD in USAID funding, was awarded to the SA2 in mid-September 2024 to specifically assist with the implementation of the USG National Standards Strategy for Critical and Emerging Technologies (NSSCET)

under its Line of Effort #8: Facilitate broad representation in standards development globally. More information about this obligation and new area of work will be available in the forthcoming project quarter. Also during Q4 2024 the team is organizing launch events in the U.S. and Geneva with key stakeholders and will also have a work plan for this activity finalized and shared with USAID.

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

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.

Implementation continued during Q3 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 monthly 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;
- Notably under Q3, traceability has been considered for addition to the scope of TC 345, as there was a discussion at the Plenary and a follow-up ballot that have been approved. The ISO/PC 348 leadership has a proposal to add traceability PC 348, so both committees will be monitored to understand how traceability is being managed and if there is any overlap with other committees going forward in 2025.

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

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 Q1 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.

Continuing from the work reported under the Q2 2024 report, ANSI staff members 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, staff reported that they encouraged the ANSI President, Joe Bhatia, to vote to approve the MOU on the ISO Council Ballot. The MoU was approved and signed in July 2024 and ISO CS hosted a training session for PC 343 members in August 2024. During the session, Marco Rossi, the ISO TMB Secretary, explained how the MOU would be implemented and stressed that while the UNDP comments and submissions should be carefully examined and considered, PC 343 P-members have control of the development of all projects assigned to the PC.

The ISO/UNDP PAS 53002:2024 – Guidelines for Contributing to the United Nations Sustainable Development Goals (SDGs) has been officially published in September 2024. They may be accessed via ISO/UNDP Guidelines for the SDGs at no charge here: <https://bit.ly/4glKGZQ>.

The U.S. TAG actively participated in the development of this guidance document. At the ISO General Assembly meeting the publication of ISO/PAS 53002 and the partnership between ISO and UNDP was presented in an interview with Noelia Garcia Nebra, Head of Sustainability at ISO and Marcos Neto, UN Assistant Secretary-General and Director of UNDP's Bureau for Policy and Programme Support.

The US TAG to PC 343 will meet on 17 and 18 October 2024 to finalize the US Comments on the “National Body Commenting Period” for ISO WD 53001. PC 343/WG I is scheduled to meet virtually the week of 17 November 2024 to dispose of the National Body comments submitted in response to the “National Body Commenting Period”.

AFRICA

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

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

Inteleos, through its Country Lead, has been in constant touch with leaders within Kenya’s Ministry of Health (MOH), as well as both the private and public healthcare systems to ensure policy is reflective of in-country needs. Inteleos has provided clinical expertise for the policy and what should be required both in education as well as certification.

Since July 2024, there have been several stakeholder meetings that have resulted in the MOH agreeing on a lengthy policy around primary maternal health providers practicing OPOCUS; basic obstetric point of care ultrasound. While the launch of the policy was originally scheduled to take place in September 2024,

the MOH have pushed the official launch to early 2025. This delay is in the hope that President Ruto will ceremoniously be involved in the policy launch.

In September 2024, some members of the Inteleos team traveled the UNGA79 and while there, had pivotal meetings with both Amref Health and the Center for Public Health Development (CPHD). Current partner Amref International University has provided an in-depth proposal to utilize our curriculum within their established Learning Management System (LMS) to reach up to 600 nurses and midwives with didactic and practical training coupled with certification. Inteleos is now in talks to bring together larger Amref for a permanent program within the university to scale in multiple countries.

Additionally, part of the Inteleos team met with CPHD, a scaling partner on the private side for training and certification. CPHD has been a stakeholder partner in the policy work and works closely with the MOH.

For content and certification, development has continued on a more basic OPOCUS certification that is aligned with the Kenyan policy and research in the region. This certification is being created with Subject Matter Experts (SMEs) from Sub-Saharan Africa, to best reflect local scope of practice.

Finally, there has been extensive work preparing for not only the Maternal Summit in Nairobi in November, but also the first cohort of trainers and clinicians to be trained at the same time as the Summit is taking place. That training will take place at Mindray's training facility within Kenyan Medical Training College (KMTC) the week of November 11, 2024.

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

Administrative update: The project was originally 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 was approved August 7, 2024. The modified approved budget increases the project total to \$210,000.

Activity #18.1 - ISO 17065 Needs assessment/baseline – gap analysis

NSF's Beverage Quality/Food team has begun an in-depth ISO 17065 gap analysis and process mapping of ASN's certification process.

NSF reviewed ASN supplied documents, including PR-001 Certification Procedure and is creating a detailed process map of ASN's certification process. NSF sent several questions to ASN for further information, which ASN responded to. These questions sought clarification on several aspects of the certification process, including the use of specific forms, document sharing and communication procedures with applicants, and the renewal process for certified clients. Additionally, it requested the confirmation of lab relationships, the certification of additional ECOSTAND standards, translated organization flow charts, and updated accreditation certificates for ISO 17065 compliance. These documents are being further evaluated by NSF for the purpose of process mapping.

NSF will be sharing with ASN a document prepared by NSF's Quality Assurance team that is used to evaluate a company's compliance with ISO 17065 requirements. Once completed by ASN, the document will act as a road map identifying areas that need addressed prior to accreditation.

Activity #18.2 - 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). The Beverage Quality/Food team has asked ASN if they are able to provide documents referenced in in ECOSTAND. NSF has received these documents and will begin a comprehensive review in Q4 2024. NSF's Laboratory team has purchased the identified methods.

Activity #18.3 - Review, development, and translation of training materials for ISO 17065

NSF's Beverage Quality/Food team completed an initial inventory and review of the documents submitted by ASN. With the initial document transfer, three (3) documents were provided in French with English summaries (DS 1 decret 2002-746 du 19 julliet 2002; DS 2 Recepisse de declaration d'association; and DS 3 Statut ASN). At this time, NSF's Beverage Quality/Food team is undergoing an in-depth review of the documents to inform the ISO 17065 gap analysis and process mapping.

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.

Since Q4 2023, IAPMO has been working with the Ministry of Public Works on updating SNI 8153:2015 (Indonesia's Plumbing Code). This past quarter IAPMO participated in in-person and virtual meetings with the technical committee discussing proposed changes. Included in this discussion is a new reference to SNI 122:2022 which is now included in the draft revised standard. By adding SNI 122:2022 as normative reference, this will encourage the industry to seek testing and certification to this standard. The next meeting with the SNI 8153 Technical Committee is scheduled for November 2024. The goal for finalizing SNI 8153 is Q2 2025. Additionally, as part of its faucet standard effort, IAPMO was instrumental in the development of SNI 9146:2023 for stainless steel sinks. In parallel to its work to mandate SNI 122, IAPMO is also working with APIN and other industry stakeholders to mandate SNI 9146:2203. The Ministry of Industry anticipates that this will be accomplished end of Q2 2026.

In February 2025, the United States will be hosting an APEC summit on plumbing standardization at SOM I in Korea. IAPMO is also in discussions and will be meeting in person in November with Ministry of Industry staff regarding their involvement in this summit to highlight many of the activities outlined in this report.

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

As mentioned in the introduction of this report, this activity has concluded its post implementation period during Q3 2024, and the final report for the MDRC has already been shared with USAID.

The implementing partner AdvaMed has expressed, with ANSI's support, their desire to continue to work under the Standards Alliance program should it continue beyond 2026.

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 #13 – Support for critical minerals standardization coordination

The most current challenges are the approval of technical projects, which has not taken place yet. Since the technical work depends on when proposals are brought forward to TC 345 by a country or liaison organization, work at the international level has been slowed down. This may lead to delays going forward under Q1 2025. To address this issue the team is seeking to increase coordination with the TAG chair to keep the technical project approval on top of the agenda.

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

As a result of Inteleos' unique approach, with an emphasis on commercial sustainability, additional time is required through the program to ensure that partnerships are built that seek to invest in Kenya, by Kenya and for Kenya. Political challenges, which can delay forward movement and outcome achievements, are still significant in the implementing area and remain a focus of challenge reduction activities. Additional

challenges are a result of the significant effort necessary to bring together the diverse public and private stakeholders necessary for objective achievement towards a single goal.

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.

An additional challenge is that PC 343 has agreed to skip the Committee Draft (CD) stage of the ISO process for ISO WD 53001. This decision was taken via committee ballot, which the US and 6 other P-members did not support. PC 343 leadership has circulated the latest working draft of ISO 53001 for an 8-week “National Body Commenting Period”, which is not a step in the standards development process or documented in the ISO Directives, Part 1. ANSI staff and the US TAG will closely monitor the disposition of the National Body comments received to ensure that all comments received are disposed of by PC 343.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date
17	N/A	Global	ISO CS training session for PC 343 members	August 2024

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

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

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 no training offered during Q3 which aligns with the targeted number. There is one training/ workshop scheduled for Q4 2024.

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

For Activity 17, there was one webinar offered during Q3 which aligns with the targeted number. There are two trainings and advocacy engagements scheduled for Q4 2024.

5. LESSONS LEARNED

Activity #13 – Support for critical minerals standardization coordination

The team has found out that given the recent formation of the TAG, gathering key US experts for their participation in the standards development in the Critical Mineral sector is turning out to be more lengthy than originally anticipated.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity#	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
13	N/A	Global	N/A	US TAG to TC 345 Meeting	January 2024	Virtual	TBD
17	N/A	Global	N/A	US TAG to PC 343 Meeting	October 2024	Virtual	Yes
17	N/A	Global	N/A	PC 343/WG I Meeting	November 2024	Virtual	Yes
16	N/A	Kenya	N/A	Summit: National OPOCUS Certification in Kenya	November 13-14	Radisson Blu, Arboretum, Nairobi	Yes
16	N/A	Kenya	N/A	TOT and Clinical training	November 11-15	KMET	No