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Standards Alliance: Phase 2

Quarterly Report

Q4 October 1st- December 31st 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, Senegal, Indonesia, Indo-Pacific (regional)
Reporting Period:	Q4 October 1st - December 31 st 2024

I.I 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.

SA2 Support for the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET)

Beginning in 2024, the SA2 will include activities that align with Line of Effort #8: Facilitate broad representation in standards development of the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET). The USG NSSCET was published in May 2023, renewing the USG commitment to the rules-based and private sector-led approach to standards development, and complement the innovative power of the private sector with strategic government and economic policies, public engagements, and investments in CET. The Strategy outlines how the U.S. Government will strengthen U.S. leadership and competitiveness in international standards development, and ensure that the “rules of the road” for CET standards embrace transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and broad participation. Further information on how the Strategy will be implemented is available in the Implementation Roadmap published in July 2024. In particular, OUTCOME 6 “Enhance USG and like-minded nations’ representation and sustain influence in international standards system,” includes the role of USAID-funded technical assistance in helping low and middle-income countries (LMIC) harness digital technologies to promote economic growth and trade. The SA2 will support activities aligned with the NSSCET in partner countries in Latin America, Africa, and Asia.

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The fourth 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); water and sanitation activities in Senegal and Indonesia; and support around medical devices for ultrasound care in Kenya. In addition, following the obligation of \$1.5 million federal funds to the Standards Alliance to focus on facilitating broad representation in standards development for critical and emerging technologies, ANSI organized launch events in Washington, DC and Geneva, and developed an updated work plan to program these funds.

During this reporting period Senegal's Bottled Water Certification Scheme has progressed well due to the development of several key documents for the certification process by NSF's Quality Assurance team.

In Indonesia, the PT IAPMO Group achieved a significant milestone with the accreditation of its faucet testing laboratory to test to SNI 122:2022. Additionally, IAPMO initiated and progressed multiple workstreams to emphasize the importance of SNI 122:2022 to the plumbing industry.

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

Implementation continued during Q4 2024, where ANSI managed a U.S. TAG to participate in the activities of ISO/TC 345 on Specialty Minerals and Materials by:

- Continuing to maintain and update 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;
- Continuing 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;
- Continued to monitor traceability as part of the scope of TC 345 and in PC 348 to understand how traceability is being managed and if there is any overlap with other committees going forward in 2025.
- Continued liaising with the US/TAGs to ISO/PC 348, ISO/TC 298, and ISO/TC 345

There will be a U.S. TAG meeting in the 3rd quarter to coordinate input into the Ad hoc group activities of the TC. The next TC meeting has not been confirmed yet, but will probably be in 2nd/3rd quarter 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 Q3 2024 report, the US TAG to PC 343 meet on 17 and 18 October 2024 to finalize the US Comments on the “National Body Commenting Period” for ISO WD 53001. Additionally, PC 343/VG 1 meet virtually the week of 17 November 2024 and week of 13 January 2025 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 (IPOCUSUSA): Better Maternal Outcomes through Ultrasound Education, Workforce Development, Policy Advocacy and Certification

Partner country: Kenya

Implementing Partner: The Inteleos Foundation

The OPOCUS Certification Summit in Nairobi (November 12-14, 2024) marked a significant milestone in this activity and Kenya's maternal healthcare transformation.

Kenya is implementing a groundbreaking policy to enable nurses and midwives to conduct basic obstetric ultrasound scans, aiming to improve maternal health outcomes across the country.

Key Developments

- Policy Implementation:
 - A new national policy now includes Point of Care Ultrasound certification for primary maternal clinicians
 - The complete policy launch is scheduled for early 2025

Progress Made

- Comprehensive training protocols have been established
- Master trainers must now possess both OPOCUS certification and valid practice licenses
- The initiative has gained support from multiple stakeholders, including the Ministry of Health and professional associations

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.

Inteleos also submitted an additional report about the activities of the Summit, which will be shared on the Inteleos and Standards Alliance websites, and other relevant locations.

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

Partner country: Senegal

Implementing Partner: NSF International

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

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

This quarter, NSF's Quality Assurance team finalized the ISO 17065 Checklist which will be used to evaluate ASN's compliance with ISO 17065 requirements. NSF reviewed ASN's internal documents and procedures to develop this ISO 17065 Checklist with references to ASN's protocols and policies that demonstrate compliance with each ISO 17065 requirements. The checklist identified gaps in ASN's documentation as well as questions about ASN's processes and policies. NSF will meet with ASN in Q1 2025 to review the checklist.

Additionally, NSF has completed and shared a map of ASN's Certification Process Flow. This map includes the processes for new clients and renewal every third year, as well as annual surveillance. The process map identifies gaps in ASN's certification processes and/or documentation, which NSF will review with ASN in Q1 2025.

NSF's Quality Assurance team also developed an Accreditation Responsibilities document for ASN. This document will be used to document the board, group of persons, or person having authority and responsibility for each aspect of certification.

Activity #18.2 - ECOSTAND 022 review by NSF Laboratories, Auditing Staff and Standards team

NSF's Beverage Quality and Laboratory team members have initiated a comprehensive review of ECOSTAND 022 (in English), as well as additional standards referenced in ECOSTAND 022: ECOSTAND 17, ECOSTAND 50, ECOSTAND 52, and CAC/GL 50 – 2004. NSF is beginning to develop an audit checklist, client-facing documents, and any other documents deemed necessary for successful certification implementation.

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

NSF's Beverage Quality/Food team is undergoing an in-depth review of the documents to develop training materials.

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.

PT IAPMO Group achieved an important milestone on October 3, 2024 as its faucet testing laboratory received accreditation from KAN to test to SNI 122:2022. The lab has had capacity to test to SNI 122:2022 since Q2 2023.

As previously reported, the Ministry of Industry determined that it cannot make SNI 122:2022 mandatory and IAPMO cannot proceed with developing the RIA until the standard has been normalized with Indonesian manufacturers. To support the normalization and implementation of SNI 122:2022, IAPMO has initiated several additional workstreams to complement the standard.

1) Incorporating SNI 122 (faucets) into the revised SNI 8153 (plumbing systems)

- IAPMO has been working with the Ministry of Public Works on updating SNI 8153:2015 (Indonesia's Plumbing Code). IAPMO participated in in-person and virtual meetings with the SNI 8153 Technical Committee to include a new reference to SNI 122:2022. This quarter, the standard has been added 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 SNI 8153 Technical Committee took place in November 2024. IAPMO provided training to technical committee on the 2024 Uniform Plumbing Code so that the revision of SNI 8153 can incorporate the latest, applicable provisions. SNI 8153 is due to be finalized in Q2 2025.

2) Starting the process to mandate SNI 9146 (stainless steel sinks)

- 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 9146:2023. The Ministry of Industry anticipates this will be accomplished by the end of Q2 2026.

3) Working to highlight Indonesia's efforts at the upcoming APEC meeting on plumbing standardization

- In July 2025, the United States will be hosting an APEC summit on plumbing standardization at SOM 3 in Incheon, South Korea. IAPMO met with Ministry of Industry staff regarding their involvement in this summit to highlight IAPMO's activities in Indonesia. The Ministry has tentatively agreed to participate, pending a formal invitation from APEC, and share Indonesia's experience in standardizing plumbing components.

4) Developing an IWSH project to showcase the need for these plumbing standards.

- A potential project site was visited in November 2024 with Ministry of Public Works, Ministry of Industry, and BSN. The results of this site survey are currently being evaluated by participating stakeholders to determine viability.

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

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 USG NSSCET Related Activities Implementation Progress

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

Activity #19 – Support for implementing the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET) (new addition to work plan in Q4)

Global

ANSI developed the work plan for the activity during Q4, 2024. As part of this work plan, the team developed 10 sub-activities targeting NSBs across each region and directly targeting specific countries with engagements on specific CET sectors. These include support to NSBs in Africa, Latin America, South and Southeast Asia, as well as engagements with Mexico on AI. Additionally, the work plan includes activities partnering with organizations such as ITC, JTCI, AdvaMed, and with higher learning institutes in Africa. Implementation of the sub-activities began in Q4, 2024 with Activity #19.1 with the remaining activities scheduled to begin in 2025.

Activity #19.1: U.S. and Global launch activities for SA2 CET work

ANSI and USAID organized a launch event on October 29, 2024, at ANSI's headquarters in Washington, DC. The launch event provided a detailed overview of the project, and sought support for the implementation of the USG NSSCET by enhancing standards development and capacity building in under-represented regions. Presenters explained the new funding opportunity and proposals under the SA2 expansion and addressed areas listed in the USG NSSCET that are priorities to members and U.S. stakeholders, including:

- artificial intelligence and machine learning;
- biotechnologies;
- digital ID infrastructure and distributed ledger technologies;
- renewable energy generation and storage;
- quantum information technologies;
- semiconductors and microelectronics; and
- communication and networking technologies.

On November 7, a second launch event was hosted jointly by ANSI, USAID, and the International Trade Centre (ITC) for the launch of the SA2 Critical & Emerging Technology activity, as well as a separate new project – a partnership of the ITC and USAID that also focuses on standards training. This event was held during the World Trade Organization (WTO) Technical Barrier to Trade (TBT) meeting at the WTO headquarters in Geneva, and featured opening remarks of David Bisbee, Deputy Chief of Mission, Office of the United States Trade Representative (USTR).

2.5 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. Even though this challenge persists, IAPMO has launched several other workstreams, reported above, that will further this and related goals in Indonesia.

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. Recently the TC 345 has formed 2 ad hoc groups to begin studying the work. One ad hoc group, for Platinum group metals, was formed 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 - Vocabulary - Part 1: Precious metals and units.

Another ad hoc group that will focus on gathering the requirements and needs involving other metals/minerals

The U.S. TAG is doing outreach to find individual experts to participate in these activities, while at the same time monitoring the work.

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

Operationalizing the national policy and guidelines that are now in place in Kenya is the biggest forthcoming challenge. This will be a massive undertaking bringing together government, private sector, academia and professional societies. There is tremendous momentum and the ongoing challenge will be to ensure barriers are not put in place just for political gain. The need to ensure funding is designed to accelerate implementation to train and equip healthcare professionals to advance practice and achieve impact in improving maternal and fetal outcomes is vital.

Healthcare challenges are also present. 47 percent of Kenya's population lacks access to essential diagnostic services, and most maternal deaths occur in referral hospitals, where only 70 percent have necessary equipment. There is an opportunity for strategic multistakeholder engagement and partnerships to achieve scale and impact in both training and certification of Kenyan designated healthcare professionals.

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

As most of the PC 343 WG 1 meetings are held virtually at times favoring European participants, it has been somewhat difficult for US experts to attend WG 1 meetings. ANSI staff successfully requested that the Chair and Committee Manager of PC 343 rotate the timing of the WG meetings to allow increased participation from experts outside of Europe which has allowed increased participation from US experts in WG 1. Unfortunately, PC 343/WG 1 has been scheduling its most recent meetings at times that are inconvenient for US experts (very early in the morning) which is impacting US participation in the activity. ANSI has sent another request to the Convenor and Committee Manager to ask that meeting start times be rotated again to allow for increased participation.

During this reporting period, US experts have noted some concern with the progression of ISO WD 53001, namely the prioritization of three SDGs and the Convenor's deference to the UNDP. ANSI staff, including Steven Cornish (ANSI's ISO TMB Representative) and the TAG Chair have met to discuss how best to address this situation. ANSI staff are developing a background document on the possible issues of PC operation and will seek TAG approval before asking Mr. Cornish to raise the issues at the TMB meeting in March 2025.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	
17	N/A	Global	US TAG to PC 343 meeting to finalize US comments for ISO WD 53001	October 17 and 18	15 US experts
19	19.1	Global	USG NSSCET Activities US Launch Event	October 29	33 total in-person and virtually
19	19.1	Global	USG NSSCET Activities International Launch Event	November 7	45 total, 30 men, 15 women. Mostly government, representatives to the WTO.
16		Kenya	Certification Roundtable	Nov. 12	16 total, 8 women, 8 men. Professional associations, academia, accreditation and standards associations, clinicians
15		Kenya	OPOCUS Certification Summit	Nov. 13-14	About 50 total, fairly evenly split by gender. MOH, private, public, professional associations, accrediting bodies, clinicians, healthcare systems, academia.
16		Kenya	OPOCUS training	Nov. 11-15	Mostly women (nurses and midwives) about 15 total. Private (RUAI

					Hospital), with sponsorship from Mindray.
I7	N/A	Global	PC 343/WG 1 meeting to dispose comments submitted	November 17	76 international technical experts

4. RESULTS ACHIEVED

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

Activity #13 – Support for critical minerals standardization coordination

Participated in the approval of the 2 new ad hoc groups.

Coordinated with US/TAG for ISO/PC 348 on the new scope and potential overlap with ISO/PC 348 and ISO/TC 345.

Coordinated with US/TAG for ISO/TC 298 and ISO/TC 333 on the new scope and potential overlap with ISO/TC 345.

Activity #19 – Support for implementing the United States Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET)

Held 2 well attended launch events in the US and internationally and received draft concept notes from potential implementing partners for future sub-activities.

Performance Indicator #2: Number of trainings conducted about the value of using 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

Three events were conducted in Q4: the Certification Roundtable, the OPOCUS Certification Summit, and OPOCUS Training.

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

For Activity 17, there were two trainings and advocacy engagements which occurred in Q4 2024, in accordance with the set targets.

The PC 343 Committee Manager issued WD 4 for comment at the committee level, setting the Q4 goal for the TAG to review WD 4 and provide feedback. The activity team successfully organized TAG meetings to review the comments received and finalize the U.S. consensus position for submission on the ISO balloting portal. These meetings fostered meaningful discussions and effectively prepared the U.S. WG

I experts for the multiple Q4 WG 1 meetings. During these meetings, U.S. perspectives were presented, and international comments on WD 4 were reviewed and addressed.

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.

Activity #7 – Increase the Flow of WASH Services

IAPMO is still working through the challenges of getting the Ministry of Industry to mandate SNI 122. The Ministry is hesitant to take that step until there are an ample number of certified products available. This past quarter, IAPMO developed several new work streams targeted on helping the Ministry overcome its concerns. We are looking forward to continuing to advance this work and report on its outcomes.

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

There is tremendous momentum to operationalize the new policy around OPOCUS, and true buy-in. This is a pivotal point to start Training-Of-Trainer trainings with certification in an organized way in priority counties, as identified by the MOH. Another key piece is to keep educating on the importance of standards and certification and what is certification (not a certificate of training completion).

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

On January 27, ANSI received a Suspension Notice from USAID, requiring all activities under the Standards Alliance to cease. As such, no activities are planned for the next quarter.