



*Standards Alliance: Phase 2*

# Quarterly Report

*Q2 April 1<sup>st</sup> - June 30<sup>th</sup> 2026*

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# Table of Contents

|                                                   |    |
|---------------------------------------------------|----|
| 1. PROGRAM OVERVIEW/SUMMARY.....                  | 2  |
| 2. ACTIVITY IMPLEMENTATION PROGRESS.....          | 4  |
| 3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT..... | 15 |
| 4. RESULTS ACHIEVED .....                         | 16 |

# I. PROGRAM OVERVIEW/SUMMARY

|                                                      |                                                                                                                       |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| <b>Program Name:</b>                                 | Standards Alliance: Phase 2                                                                                           |
| <b>Activity Start Date and End Date:</b>             | July 12, 2019 – July 11, 2026                                                                                         |
| <b>Name of Prime Implementing Partner:</b>           | American National Standards Institute (ANSI)                                                                          |
| <b>Agreement Number:</b>                             | #7200AA19CA00012                                                                                                      |
| <b>Name of Subcontractors/ Subawardees:</b>          | NSF, IAPMO                                                                                                            |
| <b>Geographic Coverage</b> (cities and or countries) | Brazil, Colombia, Paraguay, Mexico, West Africa (regional), Ghana, Kenya, Senegal, Indonesia, Indo-Pacific (regional) |
| <b>Reporting Period:</b>                             | Q2 April <sup>1st</sup> – June 30 <sup>th</sup> 2026                                                                  |

## 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 stable and reliable markets for U.S. goods, be more prepared for bilateral trade agreements, and be more capable of protecting their citizens from hazardous goods.

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

The implementing partner for this cooperative agreement is the American National Standards Institute (ANSI). ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. ANSI's mission is to enhance U.S. global competitiveness and the American quality of life by promoting, facilitating, and safeguarding the integrity of the voluntary standardization and conformity assessment system. ANSI's role as a coordinating body and the bridge between the private and public sectors uniquely positions the Institute to build partnerships and foster collaborative solutions that address both national and global priorities. ANSI is also a membership organization, providing members with the broadest access to up-to-date standards policy information and opportunities for participation, leadership, and influence. Finally, ANSI promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

The Standards Alliance Phase 2 includes activities in markets representing a variety of geographical regions and levels of economic development, subject to the agreement of U.S. Government. In consultation with the U.S. government, and private sector experts, ANSI will select the countries/regions based on demonstrated commitment and readiness for assistance, as well as U.S. private sector interest and development impact. ANSI expects to engage at both the national and regional level where appropriate and to involve partners in the Latin America, Africa, Middle East/North Africa, and Indo-Pacific regions. SA2 focus on supporting U.S. leadership around Critical and Emerging Technologies, including Critical Minerals

Beginning in 2024, the SA2 activities have directly supported the USG objectives to advance U.S. leadership around CET and critical mineral standards to ensure national and economic security. This work underlines the commitment to the rules-based and private sector-led approach to standards development, leveraging the innovative power of the private sector with strategic government support via economic policies, public engagements, and investments in CET. The activities focus on emerging economies in Africa, Asia, and Latin America, and supports greater U.S. influence in related international standards activities. Implementation aims at counteracting potential unilateral standards imposition, and promoting integrity and transparency in the international standards system, ensuring that the U.S. private sector plays in key role in the development of those standards, ensuring U.S. exports facilitation and a more favorable US trade balance with partner countries. It also addresses goals such as improving capacity of countries to develop and implement standards, opening new markets and strengthening U.S. supply chains, and improving readiness to take part in digital transformation and adopt emerging technologies.

## 2. ACTIVITY IMPLEMENTATION PROGRESS

### 2.1 Progress Narrative

The SA2 resumed implementation during the second quarter of 2025, following a suspension of activities pursuant to the Executive Order on [reevaluating and realigning the United States foreign aid](#) of January 20, 2025. All program activities and outreach ceased between February 26, 2025, when ANSI received a termination notice, and May 20, 2025, when ANSI received a Termination Recission. A contract modification allowing for activities to resume was also sent on June 6, 2025.

Upon receipt of the contract modification, ANSI developed a revised Work Plan for Year 7 of the SA2 (2025-2026) and shared this with the U.S. Government on June 12, 2025. The SA2 was subsequently transferred to the State Department for administration on July 10, 2025. Following the workplan development and transfer of administration to the State Department, the SA2 has resumed implementation of its activity around critical minerals. This is to continue supporting the USG's objective of increasing domestic mineral production as highlighted by the Executive Order of April 24, 2025 "Unleashing America's offshore critical minerals and resources" to further the national security and economic interest. The standards being developed impact the way these minerals are classified, sampled, tested and analyzed, traced and labeled. Since 2024, ANSI, as the U.S. representative to the International Organization for Standardization (ISO) has leveraged its unique position to facilitate broad U.S. participation in and leadership of ISO standards development around critical minerals.

ANSI's monitoring of the critical minerals standards landscape in the U.S. suggests that there is activity underway to solidify consensus on the U.S. strategy towards critical mineral standardization, particularly international standards. This activity plays a particularly critical role in sustaining support from allied countries and strengthening U.S. influence in international standards in this space; and therefore, has been the emphasis of the SA2 work during the last quarters of the program's implementation.

Additionally at the end of Q1 2026 the program received the authorization to resume implementation of critical and emerging technology activities, as well as those related to water and sanitation. These activities restarted in Q2 2026, and trainings on AI, Cloud Computing, and Cybersecurity international standardizations were organized in May and June 2026.

Finally, the program also implemented a training on bottled water certification in Senegal and final engagement between IAPMO and Indonesian water authorities in June 2026, helping to create a more predictable and enabling business environment for U.S. companies engaged in safe drinking water, bottled water production, certification and trade.

## GLOBAL

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

### **Activity #13 – Support for critical minerals standardization coordination**

ANSI has continued to administer the U.S. TAG to TC 82/SC 7 and TC 345 to build awareness that enables allied developing countries to participate in standards development for critical minerals; and to strengthen coordination within the U.S. stakeholder group, including U.S. government agencies, to align future work within ISO with U.S. strategy on critical minerals.

During this quarter ANSI staff led the recently established ISO Critical Minerals Coordination Group (ICMSCG) and coordinated U.S. input on a report from the ISO Technical Management Board Critical Minerals Coordination Committee (ISO/TMBG/CMCC), which has been submitted to the ISO/TMB for review. This was the first review of an ISO/TMBG/CMCC report, so establishing a clear, unified U.S. position was essential. The quarterly ICMSCG meeting took place on April 24, 2026. ANSI's TMB member will submit the official U.S. response on behalf of ANSI when ready.

#### **ISO/TC 82/SC 7 activity –**

ANSI staff managed U.S. TAG coordination with their international counterparts to disapprove the proposed work item and support U.S. leadership for the committee. An ad hoc group was formed- **Ad Hoc Group 5 on traceable critical minerals**. ANSI staff is supporting the AHG 5 as Secretary.

The TAG met on May 8, 2026 where ANSI staff provided training on ISO participation and standards development process and continue to manage the U.S. input on the current active work program.

- *ISO 20305: 2026 Mine closure and reclamation — Vocabulary*, was published during the quarter.
- *ISO/WD 25603 “Underground mine tailings backfill guidance”* All three U.S. WG 5 experts had registered to attend the ISO/TC 82/SC 7 WG 5 Meeting on May 17th in Beijing, China.
- *ISO/CD 8238 “Sustainable mining and mine closure — Social aspects”* Supported U.S. TAG provided comments on the committee draft. ANSI staff worked with Monique Parker from Elevra to coordinate the U.S. comments on the draft standard using the OSD.
- *ISO/WD 25412 “Finding value in mining wastes”* U.S. TAG determined this an important activity, but we do not have a U.S. expert participating. ANSI staff recruited Kathleen Vello, Regulatory Impact Analyst, Policy and Regulatory Analysis Branch, Office of the Administrator, U.S. Environmental Protection Agency to attend a working group meeting, but she cannot commit to participation.

An additional new proposal was received on June 26, 2026 on *Mine wastewater monitoring and assessment* and is currently out to the U.S. TAG member for review.

## **ISO/TC 345 activity –**

ANSI staff provided training on the how to use the Online Standards Development Portal (OSD) that is now required for participation in new ISO projects. Then coordinated the uploading U.S. comments using the OSD for each of the draft standards below.

ISO/WD 25838 “Test methods for graphite – Determination of graphitization”

- ISO/WD 25839 “Test methods for graphite – Determination of carbon content”
- ISO/WD 25840 “Test methods for graphite – Determination of trace metal element content”

A full TAG meeting took place on April 14, and included a training session by ANSI staff on how to use the Online Standards Development Portal (OSD) that is now required for participation in new ISO projects. ANSI staff then supported U.S. comment to development and support providing the comments using the OSD for each draft standard.

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

Activity discontinued in June 2025 in alignment with strategic priorities.

## **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

Activity discontinued in June 2025 in alignment with strategic priorities.

#### **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 completed the ISO 17065 assessment/baseline – gap analysis in consultation with ASN.

### **Activity #I8.2 - ECOSTAND 022 review by NSF Laboratories, Auditing Staff and Standards team**

The ECOSTAND 022 review by NSF Laboratories, Auditing Staff and Standards team is complete, with a few additions to be made by the Laboratories team.

### **Activity #I8.3 - Review, development, and translation of training materials for ISO 17065**

NSF finalized the training materials, translated them into French, and adapted them to the templates and reporting formats required by the Department of State.

### **Activity #I8.4 - Stakeholder outreach**

ASN reached out to stakeholders in coordination with NSF, after receiving approval from the Department of State, which was required before the outreach could commence.

ASN contacted 35 entities across the following stakeholder categories: bottled water producers (14), government institutions (6), laboratories and research centers (6), retailers and distributors (3), and consumer associations and NGOs (6).

### **Activity #I8.5 - Host trainings**

NSF delivered a two-day training workshop on 23–24 June 2026 in Dakar, Senegal, focusing on the application of the ECOSTAND 022 standard for bottled water certification. The event benefited from the logistical support provided locally by the Senegalese Standards Association (ASN). Reflecting the importance of the initiative, the opening session was presided over by the Director General of ASN.

A total of 26 participants attended the training, representing key stakeholders in the bottled water sector.

The workshop was conducted using a participatory approach, encouraging discussions and the exchange of experiences among participants. The program covered the requirements of ISO/IEC 17065, applicable ECOSTAND guidance documents, good hygiene practices, sampling procedures, labelling requirements, and the planning and management of certification audits.

Learning outcomes were assessed through practical case studies and a multiple-choice questionnaire (MCQ). The results demonstrated a significant improvement in participants' knowledge, with pass rates increasing from approximately 40% at the beginning of the training to 85–87% upon completion.

Participant feedback indicated a high level of satisfaction with the organization of the workshop, the quality of the training delivered, and the trainer's availability and expertise. Participants nevertheless recommended the inclusion of additional practical case studies in future training sessions to further strengthen the practical application of the concepts covered.

The activity strengthened Senegal's capacity to implement international best practices for bottled water quality and certification. By enhancing participants' understanding of the ECOSTAND 022

standard, ISO/IEC 17065 requirements, hygiene controls, sampling procedures and certification processes, the training contributed to improving the quality and safety of bottled water products in the Senegalese market.

The initiative also supported Senegal's alignment with its commitments under the WTO Technical Barriers to Trade Agreement by promoting the use of internationally recognized conformity assessment principles and certification practices. Furthermore, it contributed to the broader adoption of ISO/IEC 17065, helping to create a more predictable and enabling business environment for Senegalese and U.S. companies engaged in bottled water production, certification and trade.

In the longer term, the establishment of a robust bottled water certification framework is expected to deliver both public health and economic benefits. At the same time, certification based on recognized international standards can enhance the marketability of Senegalese bottled water products across West Africa and potentially further afield, particularly where opportunities exist for regulatory recognition and interoperability between certification systems.

## **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 significantly advanced implementation of Indonesia's plumbing regulatory modernization agenda by expanding project activities beyond development of SNI 122 toward broader implementation of the APEC Roadmap for Strengthening Plumbing Standards and Technical Regulations for Safer Drinking Water and Sanitation. Following reinstatement of project activities, IAPMO reengaged key government and industry stakeholders and coordinated closely with Indonesia's National Standardization Agency (BSN), Ministry of Industry, Ministry of Trade, Ministry of Public Works, the U.S. Department of Commerce, U.S. Department of State, U.S. Embassy Jakarta, U.S. manufacturers, and Indonesian industry partners to organize the U.S.–Indonesia Plumbing Industry Trade Mission held in Jakarta in June 2026.

The Trade Mission represented a significant milestone for the project, expanding the focus from development of a single product standard to implementation of a broader regulatory framework supporting safe drinking water systems. Through high-level government and industry dialogues, more than 50 participants advanced implementation of the APEC Roadmap by strengthening coordination among Indonesian ministries, promoting internationally aligned standards and accredited conformity assessment, addressing counterfeit and noncompliant plumbing products, and identifying future priorities for regulatory implementation, workforce development, and

market surveillance.

Although Indonesia's mandatory adoption process for SNI 122 remains under review, IAPMO continued technical engagement with BSN and other government stakeholders to identify practical measures that can encourage voluntary implementation of the standard while broader conformity assessment policy discussions continue. Rather than delaying engagement, the project has shifted toward supporting market adoption through regulatory coordination, stakeholder education, accredited conformity assessment, and implementation planning. These activities position Indonesia to move more efficiently toward mandatory implementation once the broader regulatory framework is finalized.

Importantly, the relationships, institutional coordination, and technical cooperation established under the Standards Alliance project provide a strong foundation for continued implementation beyond the period of federal funding. IAPMO expects to continue supporting Indonesian counterparts through its longstanding presence in Indonesia, ongoing collaboration with BSN and other ministries, participation in future APEC initiatives, and continued engagement with U.S. government agencies and industry partners. These efforts will focus on advancing mandatory implementation of SNI 122, expanding internationally aligned regulatory approaches to additional plumbing product categories, strengthening conformity assessment systems, and supporting future initiatives addressing counterfeit and noncompliant products throughout the region.

#### ACTIVITY 7.2: IMPLEMENTATION OF MANDATORY SN

##### *Expanding Indonesia's Regulatory Product Scheme (APEC Roadmap Implementation)*

*This activity was added as part of the budget increase and timeline extension to the Department of State on March 31, 2026. It was accepted on April 10, 2026.*

In June 2026, IAPMO convened the U.S.–Indonesia Plumbing Industry Trade Mission in Jakarta to advance implementation of the APEC International Roadmap for Strengthening Plumbing Standards and Technical Regulations for Safer Drinking Water and Sanitation. The mission brought together Indonesia's National Standardization Agency (BSN), Ministry of Industry, Ministry of Trade, Ministry of Public Works, utilities, manufacturers, and industry associations alongside representatives from the U.S. Department of Commerce, U.S. Department of State, U.S. Embassy Jakarta, and leading U.S. plumbing manufacturers. The meetings provided a unique opportunity for government and industry stakeholders to engage directly on issues affecting market access, standards development, conformity assessment, regulatory transparency, and long-term market development.

A major milestone of the mission was the first bilateral dialogue bringing together BSN, the Ministry of Industry, Ministry of Trade, and Ministry of Public Works to discuss plumbing products, drinking water systems, standards, and conformity assessment. The meetings improved coordination among Indonesian agencies by clarifying their respective regulatory responsibilities while reinforcing the need for a more integrated approach to standards development, technical regulations, conformity assessment, consumer protection, infrastructure development, and market surveillance. Throughout the discussions, participants repeatedly referenced the APEC

Roadmap as a practical framework for guiding future regulatory implementation and expanding internationally aligned regulatory approaches beyond faucets to additional plumbing product categories.

The mission also elevated counterfeit and noncompliant plumbing products as a priority policy issue among both Indonesian and U.S. stakeholders. Government officials, utilities, manufacturers, and industry representatives acknowledged that counterfeit and nonconforming products undermine public health objectives, consumer confidence, and fair competition, and emphasized that standards and certification programs must be supported by effective market surveillance, enforcement, product traceability, and accredited conformity assessment systems. These discussions helped build broader recognition of the role that internationally recognized standards and accredited third-party certification can play in strengthening Indonesia's regulatory infrastructure while facilitating trade and investment.

The participation of officials from the U.S. Department of Commerce, U.S. Department of State, and U.S. Embassy Jakarta further strengthened bilateral cooperation on standards and regulatory issues. U.S. and Indonesian officials engaged jointly with manufacturers to discuss implementation challenges, technical barriers to trade, conformity assessment practices, and opportunities for continued collaboration under the Standards Alliance and APEC frameworks. These engagements established a strong foundation for future cooperation on implementation of the APEC Roadmap, workforce development, regulatory transparency, and initiatives to address counterfeit and noncompliant plumbing products throughout the region.

Indonesia has continued developing revisions to its conformity assessment framework that would establish separate conformity assessment pathways for imported and domestically manufactured products. Current proposals would significantly expand the role of government-designated conformity assessment bodies for imported products while allowing broader participation by private-sector bodies for domestic manufacturers. U.S. government agencies, including the Department of Commerce and the Office of the U.S. Trade Representative, continue engaging Indonesian counterparts regarding the potential trade implications of these changes and the importance of maintaining transparent, internationally recognized conformity assessment systems.

Given these ongoing discussions, IAPMO has prioritized resolving broader conformity assessment policy issues before encouraging the Ministry of Industry to proceed with mandatory implementation of SNI 122. Instead, discussions with BSN during the June 2026 Trade Mission focused on identifying practical measures that could encourage voluntary compliance with SNI 122 and increase market adoption while broader regulatory issues continue to be addressed. This approach would allow for a continued implementation progress while supporting ongoing government-to-government dialogue on conformity assessment policy.

#### *Expanding Anti-Counterfeit and UPC Verification Initiative (United States)*

*This activity was added as part of the budget increase and timeline extension to the Department of State on March 31, 2026. It was accepted on April 10, 2026.*

IAPMO expanded the SA2 initiative to address counterfeit and noncompliant plumbing products entering U.S. e-commerce channels through its collaboration with Amazon. Building on previous work with U.S. manufacturers to identify counterfeit faucets posing risks to drinking water safety, the initiative seeks to improve product transparency by connecting online product listings with independently verified IAPMO certification data. The effort supports broader objectives to strengthen consumer confidence, protect public health, and promote fair competition by making it easier to distinguish legitimately certified products from those making unsubstantiated certification claims.

Throughout the reporting period, IAPMO and Amazon continued working together to develop a phased implementation plan for a pilot program that will connect Amazon product offerings directly with IAPMO's certification database. The pilot will initially focus on faucets, with a public launch anticipated in September 2026. Following successful implementation, the partners anticipate expanding the initiative to additional plumbing product categories. The collaboration complements Amazon's ongoing efforts to work with suppliers to support compliance with Safe Drinking Water Act requirements while improving transparency for consumers purchasing plumbing products online.

Lessons learned through this initiative are also informing IAPMO's international engagement under the Standards Alliance program and beyond. During the U.S.–Indonesia Plumbing Industry Trade Mission, digital product verification, product traceability, and strategies to address counterfeit and noncompliant plumbing products were incorporated into discussions with Indonesia's National Standardization Agency (BSN), the Ministry of Industry, the Ministry of Trade, and other government and industry stakeholders. These discussions highlighted growing international interest in strengthening market surveillance and leveraging digital tools to improve confidence in certified products.

At the regional level, these activities continue to complement broader APEC efforts focused on protecting consumers and promoting fair competition. During the reporting period, the Office of the U.S. Trade Representative advanced a proposal to convene a future APEC workshop examining the public health and trade challenges posed by counterfeit and noncompliant products sold through e-commerce platforms. If approved, the initiative would provide a forum for sharing regional best practices on market surveillance, product verification, digital traceability, and regulatory cooperation, while reinforcing the objectives of the APEC Roadmap for Strengthening Plumbing Standards and Technical Regulations for Safer Drinking Water and Sanitation.

## **2.2 CET Related Activities Implementation Progress**

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

#### **Activity #19 – Support U.S. leadership in Standards for Critical and Emerging Technologies**

With the contract modification restarting the SA2 program received under Q2, 2025 ANSI was able to resume supporting this activity aiming at promoting a U.S. private sector led approach for international standards development and assist professionals from allied under-represented regions by providing training and support to participate effectively in global standards-setting activities. 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, and academia across the suggested regions.

Implementation of CET activities began in Q4 2024 with hosting two events that contributed towards:

- Shedding light on the Standards Alliance Phase 2.0 CET scope and the stakeholders' engagement process
- Presenting case studies on success stories of countries and private sector engagement with the standards alliance projects.
- Engaging a broader audience by presenting at World Trade Organization (WTO) Technical Barrier to Trade (TBT) meeting at the WTO headquarters in Geneva

The main objectives of this activity were reaffirmed under the revised Annual Work Plan for SA2 shared June 12, 2025 with the USG.

In May 2026 ANSI received the authorization to resume implementation for this activity. The focus of the work under this activity in Q2 2026 was to deliver three trainings on key CETs such as AI, Cloud, Computing, Cybersecurity and how international standards in those areas are developed, as well as how medical devices are intertwined with the development of CETs.

*Activity #19.2: Coordinate with ISO/IEC JTCI leadership to support outreach and engagement by partner countries*

Leveraging ANSI's role as U.S. representative to ISO and IEC, and the secretariat of the ISO/IEC joint technical committee JTC I-Information Technology, ANSI delivered a training for the following allied partner countries on how to be more engaged in that forum and thus support US leadership in standardization around CET: Brazil, Colombia, India, Indonesia, Kenya, Mexico, Paraguay, Philippines, and Vietnam.

This global training was hosted in Geneva, Switzerland from June 15 to 19 and provided an introduction of the sub committees in JTCI that work on key sectors around CET, which are AI (ISO/IEC JTCI SC 42), Cloud Computing (ISO/IEC JTCI SC 38), and Cybersecurity (ISO/IEC JTCI SC 27).

Approximately 40 participants from the nine countries above joined this five-day training which included introductions to the relevant SCs, as well as in-depth sessions on their work, with experts from the US mirror committees to the SCs sharing their expertise and offering peer to peer knowledge-sharing opportunities. The training concluded with each of the nine countries developing a roadmap to increase their standardization efforts in those SCs to better cooperate with the US at the ISO/IEC JTC I level.

This training, to reflect the importance of a private sector led standardization development model, also included a site visit to the HP Geneva office and the ISO Central Secretariat, where the participants were able to discuss firsthand how the work at the ISO accounts for and builds upon the reality and needs of the private sector. These visits help push forward the US standardization model and its leadership to help increase trade opportunities for US companies in these countries in the medium term.

#### Activity #19.3: Advanced training for medical device regulators on biotechnology standards

ANSI's member, the Advanced Medical Technology Association (AdvaMed), executed the development and implementation of a capacity building event in Mexico City, Mexico from 15-19 June 2026.

The training included advancing capacity building for medical device regulators around Critical and Emerging Technologies with the primary objective of advancing regulatory convergence and reliance for medical devices in Mexico and Paraguay. The Critical and Emerging Technology biotechnology specializations included:

- o In-vitro diagnostics and related software
- o AI driven blood/pregnancy tests and related data
- o Biological data

AdvaMed and the Inter-American Coalition for Regulatory Convergence – Medical Technology (IACRC) continued their efforts that began under another SA2 activity focused on broader medical devices regulatory convergence, which closed in 2022. The training held this quarter allowed for a deeper implementation of modern regulatory frameworks for medical technologies in alignment with foundational Good Regulatory Practices (GRP) and use of international standards.

Nearly 150 attendees received training on foundational GRP, international standards, medical device regulatory convergence and reliance, minimization of technical barriers to trade, and improved market and patient access.

Other aspects of this project included the development and completion of a MedTech Regulatory Impact Assessment (RIA), an updated Good Regulatory Practices Checklist, a targeted Regulatory Framework & Quality Management for the Ministry of Health of Mexico (COFEPRIS), and other significant deliverables. These activities will be covered in detail in the program final report.

#### Activity#19.6: Support for national standards bodies in Latin America

Latin America is the region that is arguably the readiest to participate in standards development around CET, having received support for other US Department State funded and ANSI implemented capacity building program on this topic already; and the region that may provide the best support for U.S leadership in this field, and contain China's growing influence.

The program sought to strengthen ties between the U.S and Latin America, via another training

on CET. In May, the program organized a 3-day workshop in Mexico City focused on International AI standardization. Day-I was formatted as a U.S. -Mexico bilateral event. The subsequent days featured regional participation from Brazil, Paraguay, Colombia and Mexico.

The U.S.-Mexico bilateral meeting, which took place on May 12, consisted of a series of presentations and roundtable discussions focused on advancing artificial intelligence (AI) pre-standardization activities and their role in supporting regulatory frameworks and the development of Mexico's national AI Action Plan. The Directora General de Normas (DGN) delivered opening remarks and shared perspectives on Mexico's AI readiness. Sessions provided an overview of Mexico's current participation in the Latin American landscape for Critical and Emerging Technologies (CET) standards development, building on discussions from previous U.S. Government-hosted capacity-building initiatives.

Approximately 30 participants explored the benefits of increasing diverse stakeholder engagement in standards development activities through presentations and interactive question-and-answer sessions. The bilateral concluded with a collaborative discussion that identified priority standards-related topics for inclusion in Mexico's AI Action Plan and determined which stakeholders were best positioned to support future implementation and next steps.

On May 13 and 14, 40 participants attended the regional workshop. During these sessions, participants received a comprehensive overview of international and regional standards development, with particular emphasis on the roles of key standards development organizations, including ISO/IEC Joint Technical Committee (JTC) 1 and Subcommittee (SC) 42. The workshop also examined the UL Standards & Engagement (ULSE) standardization process, outlining the progression of concepts into recognized standards through stakeholder engagement, consensus-building, and formal approval mechanisms.

Participants were introduced to Outlines of Investigation (OOIs) as flexible, early-stage technical documents developed to address emerging technologies and safety considerations, including a detailed presentation on UL 3115 and its application to the safety evaluation of AI-based products. Additional sessions explored the critical role of regulatory frameworks in enabling investment, trade, and innovation for CET and AI. Topics included conformity assessment, differences in regulatory frameworks across economies, best practices, and the practical adoption and application of standards within regulatory contexts.

The workshop also highlighted existing standards that incorporate AI applications, such as UL 3300, and examined the relevance of the NEMA White Paper in supporting standards development for emerging technologies, connected industrial systems, manufacturing, and infrastructure. Participants discussed the role of CANENA as a regional cooperation model and considered how its experience could inform collaboration among Latin American national standards bodies.

The event concluded by highlighting the complementary relationship between regional electrotechnical harmonization, international AI standardization, and safety-focused Outlines of Investigation in strengthening technical coherence and supporting future standards development. Interactive breakout sessions enabled participants to identify barriers to participation in

international AI standards activities, assess national and regional readiness, discuss implementation challenges and priority needs, and develop country-specific action plans by outlining participation strategies, coordination mechanisms, technical follow-up activities, and realistic next steps. Representatives from Brazil and Colombia facilitated discussions with the Paraguay and Mexico country groups to encourage regional knowledge sharing and strengthen collaboration moving forward.

Finally, in support of the SA2 goal to increase partner countries' participation in international standards activities, the program supported a portion of the travel expenses associated with a technical expert from Colombia attending the meeting of the ISO/IEC JTC1/SC 42 meeting in Singapore. The expert was an alumnus of previous SA2 and State Department trainings on AI standardization, and supported half of the travel expenses on their own. The SA2 funds thus supported meaningful participation in a technical committee meeting by alumni of our training programs, and contributed to a coalition of experts led by the U.S. at the international meeting.

### 3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

| Activity # | Sub activity # | Country          | Meeting/ Event                                                                                              | Date             | Total Participants |
|------------|----------------|------------------|-------------------------------------------------------------------------------------------------------------|------------------|--------------------|
| 19         | 6              | LATAM            | Training To Support National Standards Bodies in LATAM Readiness for AI Standards Development               | May 13-14, 2026  | 70                 |
| 19         | 2              | Global           | Global Training on ISO/IEC JTC 1 Support, Outreach, And Engagement                                          | June 15-19, 2026 | 42                 |
| 19         | 3              | Mexico, Paraguay | Advanced Training for Medical Device Regulators Around Critical and Emerging Technologies 2026 (ATCET-2026) | June 15-19, 2026 | 150                |
| 18         | 5              | Senegal          | Workshop on the Application of the ECOSTAND 022 Standard for Bottled Water Certification                    | June 23-24, 2026 | 26                 |

|    |     |           |                                                        |                |    |
|----|-----|-----------|--------------------------------------------------------|----------------|----|
| 7  | 2   | Indonesia | Private Sector Led US Indonesia Plumbing Trade Mission | June 9, 2026   | 10 |
| 13 | N/A | Global    | ISO/TC 82/SC 7 TAG meeting                             | May 8, 2026    | 16 |
| 13 | N/A | Global    | ISO/TC 345 TAG meeting                                 | April 14, 2026 | 14 |
| 13 | N/A | Global    | Quarterly ICMSCG meeting                               | April 24, 2026 | 38 |

## 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 was a total of 7 training courses exceeding the 2 targeted trainings. A breakdown is presented below.<sup>1</sup>

#### **Activity #7 – Increase the Flow of WASH Services**

For Activity #7, IAMPO conducted one meeting to support the implementation of the APEC International Roadmap for Strengthening Plumbing Standards and Technical Regulations for Safer Drinking Water and Sanitation.

#### **Activity #13 – Support for critical minerals standardization coordination**

For Activity 13, the team participated in the meeting of ISO/TC 82/SC 7, the full tag meeting of ISO/TC 345, as well as the quarterly ICMSCG meeting, putting the activity above the targeted number. Many other informal meetings also occurred to support these official meetings.

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

For Activity 18, the team met its expected target of one event before the close of the quarter and the program.

#### **Activity #19 – Support U.S. leadership in Standards for Critical and Emerging Technologies**

For Activity 19, the team organized three workshop meeting the revised work plan for Year 7 objectives once funding for activities besides critical minerals were able to be reimplemented in

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

May 2026.