

U.S.–Africa Standards, Conformance, and Trade

ANSI in AFRICA

NEWSLETTER



African Stakeholders | SPRING 2024



INTRODUCING THE *ANSI IN AFRICA NEWSLETTER*

ABOUT THIS PUBLICATION

The *ANSI in Africa Newsletter* is a new engagement tool that has been added to the Institute's catalog of information-sharing resources, in addition to the *ANSI in China Newsletter* that was launched in late 2015. The newsletter is distributed to the membership and constituency of the **American National Standards Institute (ANSI)**.

The *ANSI in Africa Newsletter* includes two different versions: a special publication targeting ANSI members in the U.S., and another targeting public- and private-sector partners and relevant standardization bodies in Africa. The *ANSI in Africa Newsletter* for stakeholders in the Africa region is intended to increase understanding of the U.S. standards and conformity assessment system, and will provide the latest updates on ANSI's activities in Africa, U.S.-based standards and regulations, and share other relevant information of interest to national and regional stakeholders in Africa. The intention is for this publication to expand into a more developed newsletter in the future, depending on additional input from ANSI members and ongoing information-gathering efforts.

DISCLAIMER

The opinions expressed by the authors are theirs alone and do not necessarily reflect ANSI opinions or positions.

CONTRIBUTE

Contributions are gladly accepted for review and possible publication, subject to revision by the editors. Submit proposed news items and topic suggestions to: africa@ansi.org.

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ABOUT ANSI

Introducing the Institute

The **American National Standards Institute (ANSI)** is the official U.S. private-sector organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. Founded in 1918, ANSI is a private, membership-based, non-profit organization with its **headquarters in Washington, DC, and operations in New York.**

ANSI also has two affiliate subsidiaries, **Workcred** and the **ANSI National Accreditation Board (ANAB)**, that specialize in workforce credentialing and accreditation services, respectively. The Institute works in close collaboration with

stakeholders from the public sector (U.S. regulatory and non-regulatory government agencies), as well as the private sector (U.S. industry) to identify and develop standards and conformance-based solutions to national and global priorities.

At the global level, ANSI is the sole U.S. representative and dues-paying full member of the **International Organization for Standardization (ISO)**, and, through the U.S. National Committee (USNC), the **International Electrotechnical Commission (IEC)**. Learn more about ANSI's role at ansi.org.

ANSI'S MISSION

To enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity.

FREQUENTLY ASKED QUESTIONS

Does ANSI write standards?

ANSI is not a standards developing organization (SDO). Rather, the Institute provides a framework for fair standards development and quality conformity assessment activities to take place, and continually works to safeguard the integrity of the U.S. system. **ANSI's diverse roles** and responsive activities reflect the flexibility of the market-driven U.S. system, and help to assure its continued strength and impact in innovative standards and conformity assessment work domestically, regionally, and globally.

Is ANSI a government entity or is it designated by the government to represent the U.S. at ISO or IEC?

ANSI is not a government entity nor has it been designated by the government to represent the U.S. at ISO or IEC. ANSI is a private sector organization that serves as the official U.S. representative in regional and international non-treaty standardization forums such as ISO and IEC. Use the linked websites to learn more about ANSI's work at **ISO** and **USNC/IEC**.

Where does ANSI get its funding?

ANSI is a private non-profit organization. It is not funded by the U.S. government. Instead, ANSI receives its operating budget primarily from the following sources:

- » Standards and publication sales: ANSI sells numerous standards, including American National Standards (ANS) and ISO and IEC standards, on its webstore, **accessible here**.

- » Membership dues: ANSI has six membership categories, all of which are dues-paying: companies, government, organizations, educational institutions, international entities, and individuals. More information is **available here**.
- » Accreditation services: ANSI provides fee-based accreditation services to both standards developers and conformity assessment organizations. More information is **available here**.

These funding sources assure that no one individual or organization has undue influence over ANSI's activities.

Does the U.S. government control the U.S. standards system?

The standards system is not controlled by the U.S. government. Also, no U.S. federal government agency is responsible for overseeing the system.

Instead, there are many federal agencies that participate in the system. An example of public participation is the **National Technology Transfer and Advancement Act (NTTAA)**, which directs federal agencies to use pre-existing voluntary consensus standards in lieu of government-unique standards. The **National Institute of Standards and Technology (NIST)** is a non-regulatory federal agency within the **Department of Commerce**, and it is responsible for coordinating federal agencies' use of and participation in voluntary consensus standards. More information on the U.S. standardization system can be found in ANSI's United States Standards Strategy, **available here**.

See **page 12** of this document for information on the U.S. Government National Standards Strategy for Critical and Emerging Technology (NSSCET).



INTERNATIONAL DEVELOPMENT ACTIVITIES

Overview: Standards Alliance Program



Over the past ten years, the **American National Standards Institute (ANSI)**, in partnership with the **U.S. Agency for International Development (USAID)**, has been implementing capacity-building activities that foster the advancement of key strategic public- and private-sector U.S.–Africa relationships aimed at promoting the development of good regulatory processes, as well as the adoption of international standards and industry best practices that help meet the needs of beneficiaries in **USAID-eligible countries**.

The **Standards Alliance**, a public-private partnership between USAID and ANSI, provides technical assistance that helps increase the capacity of developing countries to implement accepted international best practices, and reduce instances of poor-quality

services, unsafe products, and infrastructure. Now in its second phase, the **Standards Alliance: Phase 2 (SA2)** program is active in Latin America, Sub-Saharan Africa, the Middle East, North Africa, and the Indo-Pacific region.

SA2 project activities provide technical assistance for partner countries to establish or reinforce legal and regulatory frameworks in various sectors, including medical devices, energy, water, and sanitation, amongst other topics. Project activities also facilitate local industry and government participation and engagement in international standards development processes and conformity assessment procedures. Furthermore, project activities build awareness and enable developing countries to prevent and remove non-tariff barriers in select industries; advance social and economic objectives; and facilitate economic stimulation, while also preserving and expanding market access for U.S. businesses.

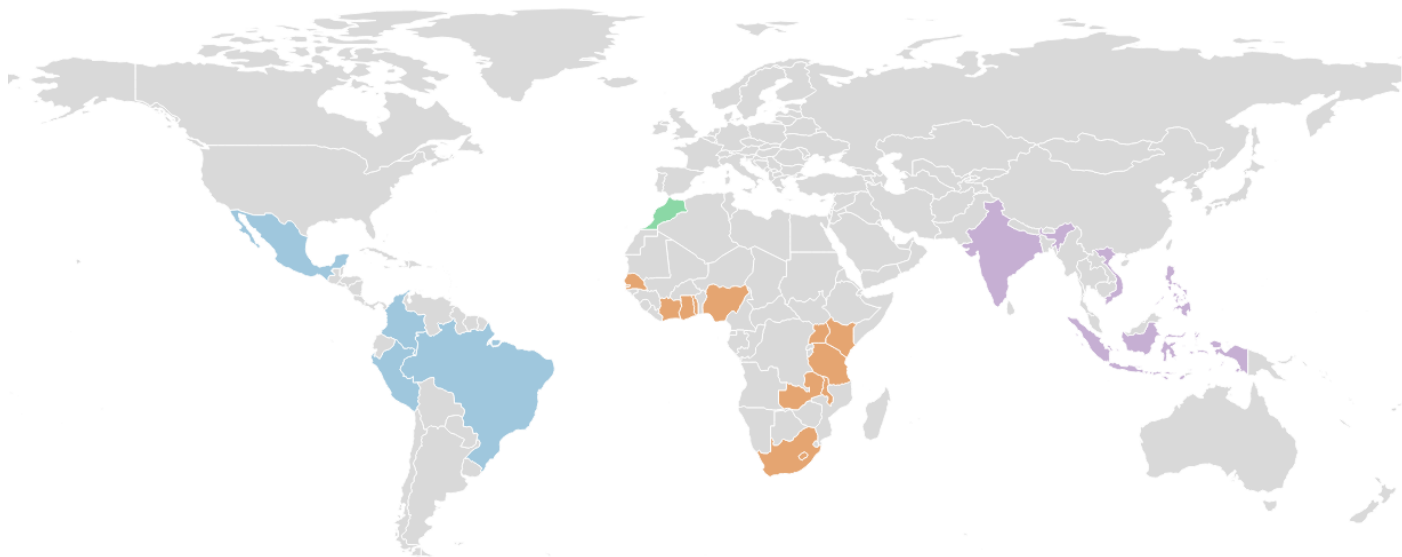
The priority areas of involvement are shaped through an interagency process guided by **USAID** and the **United States Trade Representative (USTR)**,

as well as input and endorsement from national standards bodies (NSBs), regional standards organizations, and other local government counterparts in partner countries. Furthermore, SA2 involves active collaboration with U.S. private-sector experts, government partners, and USAID missions in eligible countries and regions. Under the current implementation period, 2019–2026, the program is prioritizing projects in digital infrastructure, agribusiness, and the automotive industry, amongst other areas.

While SA2 has global activities, a majority are in various parts of Africa, including Kenya, Malawi, Zambia, Lesotho, Senegal, Cote D'Ivoire, Ghana, Nigeria, South Africa, and Morocco.

The map below includes all the countries where the Standards Alliance has implemented Phase 2 projects, and the infographic on [page 5](#) highlights the activities and milestones that have been accomplished in sub-Saharan Africa over the past year of implementation.

Standards Alliance Phase 2 Project Countries

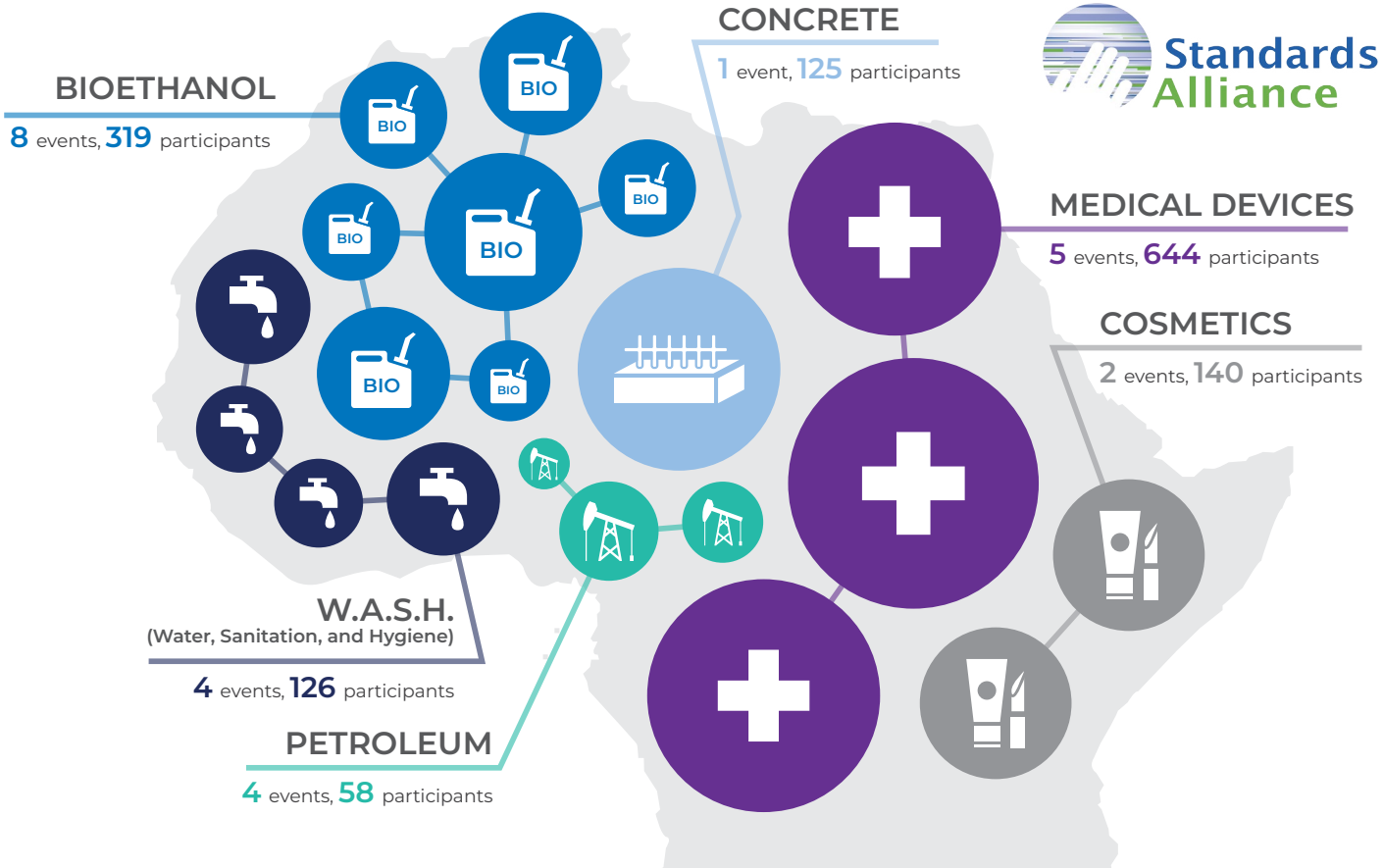


STANDARDS ALLIANCE TRAININGS AND EVENTS

PHASE 2 | JULY 2022 - JULY 2023



USAID
FROM THE AMERICAN PEOPLE



TOTAL 23 events, 1,412 participants

PARTICIPATING NATIONS

- COTE D'IVOIRE
- THE GAMBIA
- GHANA
- LESOTHO
- MALAWI
- MOROCCO
- MOZAMBIQUE
- NIGERIA
- SENEGAL
- TOGO
- ZAMBIA
- SOUTH AFRICA

UN SDGs SUPPORTED

- 6** Clean Water and Sanitation
- 7** Affordable and Clean Energy
- 8** Decent Work and Economic Growth
- 9** Industry, Innovation, and Infrastructure
- 11** Sustainable Cities and Communities
- 13** Climate Action
- 16** Peace, Justice, and Strong Institutions
- 17** Partnerships for the Goals

U.S. PRIVATE-SECTOR PARTNERS

- Pivot Clean Energy Co. (Pivot)
- ASTM International
- Advanced Medical Technology Association (AdvaMed)
- American Petroleum Institute (API)
- American Concrete Institute (ACI)
- American Water Works Association (AWWA)
- International Association of Plumbing & Mechanical Officials (IAPMO)
- Center for Water Security and Cooperation (CWSC)
- NSF International

REGIONAL AND NATIONAL STANDARDS BODIES

- Kenyan Bureau of Standards (KEBS)
- Ghana Standards Authority (GSA)
- Standards Organisation of Nigeria (SON)
- Association Sénégalaise de Normalisation (ASN)
- Côte d'Ivoire Normalisation (CODINORM)
- Economic Community of West African States (ECOWAS)
- South African Health Products Regulatory Authority (SAHPRA)
- African Organisation for Standardisation (ARSO)
- National Institute for Normalization and Standards, Mozambique (INNOQ)

MOUs SIGNED / STANDARDS ADOPTED

- ASTM International and the Malian Agency for Standardization and Quality Promotion
- NSF International and the Ministry of Health in Morocco
- ASTM E3050, Standard specification for denatured ethanol for use as a cooking and appliance fuel



PROJECT SPOTLIGHT: MEDICAL DEVICES

Kenya is Pioneering Medical Device Regulatory Convergence Cooperation in Africa

Following the launch of Standards Alliance: Phase 2 (SA2) in 2019, the program’s portfolio grew significantly to include a majority of project activities in Africa—one of which supports ANSI’s largest international development project to date in the medical devices sector.

Under SA2, USAID and ANSI partnered with the **Advanced Medical Device Association (AdvaMed)** to implement a four-year **Medical Device Regulatory Convergence Project (MDRC)** in Sub-Saharan Africa. The key goal of the four-year project is to reduce technical barriers to trade (TBTs) in the medical device sector and improve National Quality Infrastructure (NQI) in eight partner countries, including Kenya, South Africa, and Ghana. The project provides capacity building related to medical device standards and regulations, including removing technical barriers to trade, increasing patient access to high-quality PPE and other medical technologies that address COVID-19-related health challenges, and fostering private-sector engagement in the medical technology and regulatory space. The MDRC’s regional objectives in Africa are as follows:

- » Foster implementation of foundational good regulatory practices (GRPs) that promote good governance in the regulatory process, focusing on transparency, predictability, and accountability;
- » Foster implementation of medical device sector-specific convergence in regulations, standards, and conformity assessment; and
- » Assist customs authorities in understanding and following the import criteria and policies set by the health authorities addressing COVID-19.

This work is divided into two tiers, promoting both horizontal and vertical cooperation: Tier 1 prioritizes cross-sectoral GRP implementation, while Tier 2 addresses medical device sector-specific regulatory standards and conformity assessment convergence.

Kenya has demonstrated the highest level of interest and cooperation in the MDRC project, showing enthusiasm for enabling a conducive business environment for medical device production and importation in Africa. In January 2023, Kenya hosted the AdvaMed MDRC project team for a series of meetings that included the **African Organisation**

for Standardisation (ARSO), the Kenya Bureau of Standards (KEBS), and the Pharmacy and Poisons Board (PPB), amongst others, to help advance the mission of the MDRC in Kenya, and cooperation across the region. These meetings set the stage for a two-day workshop—the second in a series—that was held days later on GRP for the medical device sector, featuring presenters from each of the project countries' NSBs. This workshop was attended by 165 people from 22 countries.

Additionally, in early February, KEBS sent a delegation of representatives to the U.S. for trade and standardization-related meetings, which included a discussion of the MDRC project. In April, KEBS also attended a series of hybrid workshops on continental GRP in Pretoria and Nairobi. On November 6–10, 2023, the project convened its final medical device regulatory workshop in coordination with the Africa Medical Devices Forum (AMDF) and the U.S. Food and Drug Administration (FDA) in Nairobi.

The November event, which was attended by 150 participants from 10 African countries, fostered information exchange and capacity building between the AMDF, its members and national regulatory authorities (NRAs), and industry stakeholders covering the core international references for medical device regulatory frameworks. The workshop provided international lessons learned

from the COVID-19 pandemic and ways to mitigate future health emergencies, including implementing strong regulatory frameworks and eliminating bottlenecks in the supply chain that prevent doctors and patients from getting much-needed medical supplies. Sessions included a discussion on ISO 14971:2019, *Medical Devices - Application of Risk Management to Medical Devices*, and how it is incorporated into ISO 13485:2016, *Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*. Other sessions covered standards for regulatory use; conformity assessment activities to build regulators' confidence in device safety and performance; optimizing standards for regulatory purposes; and the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT) and its significance to health regulatory authorities.

Complementary partnership in Africa due to this work includes collaboration between the MDRC team, the South African Health Products Regulatory Authority (SAHPRA), and the U.S. Trade and Development Agency (USTDA). USTDA began working with SAHPRA in an effort to launch an Africa-focused healthcare initiative on the sidelines of the December 2022, United States–Africa Leaders Summit, which aimed at strengthening U.S.–Africa ties and fostering new economic engagement. USTDA's initiative was intended to provide a framework for engaging



Representatives of the Kenya Pharmacy and Poisons Board (PPB) meeting with the MDRC team in Nairobi, Kenya

According to Steven Bipes, vice president for global strategy and analysis and MDRC project lead at AdvaMed, the Standards Alliance has helped AdvaMed accelerate relationship building between public and private sector organizations in the medical device regulatory ecosystem, leverage cooperation, enhance training, and create substantive momentum to reduce TBTs. Bipes added that “the implementation of foundational GRPs by National Regulatory Authorities (NRAs) for medical devices, including the prioritized use of international standards as a basis for med-tech technical regulations, is a key target MDRC outcome. This helps not only in removing and preventing the emergence of technical barriers to med-tech trade and supply chain, but also in health system strengthening, assisting African partners in fully recovering from the COVID-19 pandemic, and being better prepared for future global health emergencies that affect the continent.”

and regularly convening key private-sector actors to advance a holistic healthcare agenda on the continent.

In order to be selected for the Standards Alliance project, extensive stakeholder mapping was conducted in each of the partner countries to assess needs, vulnerabilities, and gaps in medical device regulatory convergence, among other factors. Now, in the third year of the project, memoranda of understanding (MoUs) have been signed in three

project countries in Africa, and four key trainings including over 300 attendees have been completed. More than two-thirds of those who attended these trainings were private sector representatives and nearly 80 percent of the trainees were women—addressing a fundamental aspect of the project that looks to promote gender equality in standards and regulatory decision-making.

More information on the **MDRC project** is available on the **Standards Alliance Phase 2 website**.



Participants at the Standards Alliance, FDA Workshop Agenda on November 6–10, 2023, in Nairobi, Kenya



STANDARDS ALLIANCE ACTIVITY SUMMARY: Recent Capacity Building Events in Africa

In the past year, the Standards Alliance: Phase 2 (SA2) program completed several technical assistance programs, including those focusing on the cosmetics and energy sectors. Program activities targeted members of the **Economic Community of West African States (ECOWAS)** and the **African Organisation for Standardisation (ARSO)**, focusing on standards adoption and regional harmonization for cosmetics products, petroleum products, and bioethanol fuels. The following is a short list of summarized activities that took place in 2023, including the key implementing partners for each project:

PERSONAL CARE PRODUCTS COUNCIL (PCPC)

PCPC, a non-profit and leading national trade association representing cosmetics and personal care products companies, in partnership the Standards Alliance and ARSO, held its 7th and final capacity-building webinar on February 28, 2023. The webinar titled “*Labeling Practices for Cosmetics Standards*” targeted ARSO’s membership and was attended by 70 participants. More information on the event is [available here](#).



PIVOT CLEAN ENERGY

Pivot, a non-profit industry coalition that works to increase global use of bioethanol for household energy—partnered with the Standards Alliance and **ARSO** to complete a five-part virtual webinar series that began in mid-2022. The capacity-building webinar, entitled “Implementation of Bioethanol Fuel and Clean Cookstoves Businesses,” took place on February 24, 2023, and was attended by 46 participants. More information on the event is [available here](#).

Additionally, in collaboration with USAID, the Department of Commerce, and the **National and Institute for Normalization and Standards (INNOQ)**, the Standards Alliance hosted its 2nd capacity-building workshop on bioethanol standards in Maputo, Mozambique. The event took place on September 20–22, 2023, and focused on developing bioethanol economies in Maputo. It included workshop presentations; a site visit to **Yazu**, a local clean-cooking technology company and bioethanol fuel distribution warehouse in Matola, Mozambique; and a two-hour, closed-door working session with key government and industry stakeholders.

Mozambican NGOs and U.S. industry attended, including representatives from ASTM International, **U.S. Grains Council**, **Growth Energy**, **Greenlight Africa**, Green 66 Innovations Limited, and **Tongaat Hulett**, as well as government representatives from INNOQ, the **Ministry of Mineral Resources and Energy (MIREME)**, and the **U.S. Embassy**, amongst other attendees. As a result of the workshop, INNOQ adopted **ASTM E3050**, *Standard Specification for Denatured Ethanol for Use as Cooking and Appliance Fuel*, and is currently considering other relevant supporting standards. More information on the event is [available here](#).

ASTM INTERNATIONAL

ASTM, an ANSI-accredited, international standards developing organization, partnered with the Standards Alliance program to implement a two-year petroleum standards harmonization project in West Africa (March 2021 —June 2023). The project held several virtual, ASTM-specific trainings and three in-person capacity-building activities in Ghana, Nigeria and Senegal. The 3rd project activity which took place last year in Dakar, Senegal and was attended by 30 participants. More information on the event is [available here](#).

As part of the final project deliverable, ASTM in partnership with ANSI and USAID organized and hosted a U.S. Study Tour in Denver, Colorado on June 24–29, 2023. The exchange visit was held in conjunction with the **ASTM D02 Technical Committee** meetings on petroleum products, liquid fuels, and lubricants, in Denver. The program sponsored eight focal representatives from the respective NSBs and private industry in Ghana, Senegal, Cote d’Ivoire, and Nigeria to attend and participate in the petroleum standards development process for the first time, alongside U.S. participants and other international stakeholders.

During the week-long visit, the eight representatives attended various professional networking events and curated meetings with ASTM leadership. Discussions focused on applicable ASTM and API standards and testing protocols, in addition to attending key sessions of the TC. More information on the event is [available here](#).





IN THE U.S.

Public- and Private-Sector Standardization Activities

ANSI AND USTR HOST KEBS OFFICIALS TO DISCUSS THE U.S. SYSTEM

On February 9 and April 19, 2023, in collaboration with USTR, ANSI hosted two separate meetings with Kenyan representatives to discuss the U.S. standards system and potential standards activities to support the **U.S.-Kenya Strategic Trade and Investment Partnership (STIP)**, which was launched in July 2022.

The first meeting took place on February 9 at ANSI's Washington, DC office. It was held on the sidelines of STIP meetings hosted by USTR, and included representatives from the **Kenyan Bureau of Standards (KEBS)**. These meetings were organized as a follow-up to USTR's May 2022 visit to Kenya and the formalized STIP engagement that occurred in July 2022. Following their negotiations, two KEBS representatives focusing on standards and TBT notifications joined the two-hour meeting at ANSI, which included private-sector representatives from ANSI and AdvaMed, and U.S. government representatives from USTR, the U.S. Chamber of

Commerce, NIST, and the **Office of Management and Budget, Information and Regulatory Affairs (OMB-OIRA)**, among others.

As part of the discussions at ANSI, AdvaMed spoke briefly and provided updates on the Medical Device Regulatory Convergence Project (MDRC) it is implementing in Kenya under the USAID-funded Standards Alliance Program. A NIST official also provided a presentation on Technical Barriers to Trade (TBT) notifications and the role of the **U.S. WTO TBT Inquiry Point**, which is operated and overseen by NIST, an agency within the **U.S. Department of Commerce**. The presentation included a detailed walkthrough of the E-ping notification system, focusing on the public comments section and examples of notifications and comments NIST uploaded and provided specific follow-up on. Following this presentation, ANSI concluded the meeting with a brief overview of its role in the U.S. Standards and Conformity Assessment Systems. KEBS officials expressed an interest in learning more about ANSI and engaging in capacity-building activities to support the future U.S.–Kenya trade

agreement. On April 19, USTR and ANSI hosted a follow-up virtual meeting that included representatives from KEBS and the **Kenya Accreditation Service (KENAS)**, who were not present at the Washington, DC meetings. The follow up was intended to provide an opportunity for in-depth presentations and discussion on ANSI's role in the U.S. standards and conformity assessment systems. KENAS officials also had the opportunity to share information on the agency's mandate, its position, and priorities under the STIP, and highlighted areas requiring the U.S. access for Kenyan private-sector companies.

More information on the latest updates of the U.S.–Kenya Strategic Trade and Investment Partnership is [available here](#).

U.S. GOVERNMENT NATIONAL STRATEGY ON CRITICAL AND EMERGING TECHNOLOGY STRATEGY

On May 4, 2023, the Biden-Harris Administration announced the publication of a **U.S. Government National Standards Strategy for Critical and Emerging Technology (CET)** at a White House summit of standardization knowledge leaders from the public and private sectors. The strategy commits to increasing U.S. government support for the private-sector-led standards system, and calls out its alignment with the United States Standards Strategy published by ANSI.

ANSI president and CEO Joe Bhatia commended the Administration, the National Security Council (NSC), and the National Institute of Standards and Technology (NIST) for their work “developing a comprehensive document that well articulates issues, objectives, and lines of effort aimed at enhancing U.S. engagement in standardization related to CET and clearly outlines the importance of the public-private-sector partnership.”

The government strategy stresses the importance of ensuring that the “rules of the road” for CET standards embrace transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and broad participation—to support standards that are technologically sound and help American industry compete on a level playing field. It recommends increased engagement in international standards for CET and outlines how the government will prioritize efforts for a subset of CET essential to U.S. competitiveness and national security.

At the White House summit in a panel on “Standards Development to Address Global Challenges,” Bhatia shared ANSI's perspectives on U.S. priorities in standardization: “The open, rules-based standards system—following globally accepted principles for standards development—fosters growth, innovation, and opportunity,” said Bhatia. “That's why ANSI prioritizes active U.S. engagement and leadership in international venues like ISO and IEC... to assure the integrity of the standards development process built on fairness, open participation, and consensus.” In a call with the strategy's leadership team, Bhatia stated that “ANSI looks forward to working closely with NIST as a key implementing partner.”

NIST has developed a page of informational resources on the National Standards Strategy, including **fact sheets** and a link to **ANSI's U.S. Standards Strategy**.



FEEDBACK WANTED

We would appreciate your input on this newsletter and the topics you want to learn more about. Please send your feedback and questions to africa@ansi.org.



ONLINE RESOURCES



ANSI WEBSITE



STANDARDS EDUCATION
AND TRAINING



ANSI NEWS ITEMS



ANSI WEBSTORE



STANDARDS PORTAL

ABOUT ANSI



The American National Standards Institute (ANSI) is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system. For more than 100 years, the Institute has overseen the U.S. private-sector-led standards and conformity assessment system, working in close partnership with government, industry, and others to enhance the global competitiveness of U.S. business and quality of life.

ANSI represents the interests of more than 270,000 companies and organizations and 30 million professionals worldwide, through its membership, partnerships, and diverse programs and activities. More than 240 ANSI-accredited organizations develop standards that support all industry sectors and address national and global priorities.