Standards Alliance: Phase 2

Quarterly Report

Q3 July 1st- September 30th 2023

Submission Date: October 30, 2023
Version 1

Agreement Number: 7200AA19CA00012
Activity Start Date and End Date: July 12, 2019 to July 11, 2026
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This document was produced for review by the United States Agency for International Development (USAID).

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1. 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, ACI, CWSC, IAPMO
Geographic Coverage (cities and or countries)	Brazil, Colombia, Peru, Mexico, West Africa (regional), Ghana, Kenya, Mozambique, South Africa, Indo-Pacific (regional)
Reporting Period:	Q3 July 1st- September 30th 2023

1.1 Program Description/Introduction

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

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

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

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

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

SA2 Focus on Medical Devices to Support COVID-19 Response

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

2. ACTIVITY IMPLEMENTATION PROGRESS

2.1 Progress Narrative

The third quarter of 2023 continued with the implementation of activities under the approved subawards, and also saw significant progress in the development of new activities that will begin implementation in late 2023 or early 2024. Work on critical minerals and support for the creation of a US Technical Advisory Group (TAG) to ISO TC 345 on Specialty minerals has begun, and in the area of bioethanol, ANSI's partner Pivot has held a workshop in September 2023 in Mozambique. Additionally, an activity on sustainable cities in Cote D'Ivoire (CDI), as well work on standards for bottled water in Senegal are moving towards implementation in the next quarters. They both have received USAID mission concurrence and in the case of the activity in CDI (Activity #15), a training on the ISO 37101 standard which establishes requirements for a management system for sustainable development in communities is set to take place in November 2023 and updates will be provided under the next quarterly report. In Q3 good progress has, also, been made to prepare future work in medical devices in Kenya, the automotive sector in Brazil, and outreach has been made on digital infrastructure in Africa. Finally, during this reporting period MDRC achieved significant milestones: (1) in Latin America through collaboration with the Brazilian National Health Regulatory Agency (ANVISA), the Brazilian Conformity Assessment and Metrology Institute (INMETRO), and the Ministry of Industry and Development; (2) in Africa focusing on coordination and capacity building through collaboration with stakeholders, including but not limited to, the United

States Trade and Development Agency (USTDA), the New Partnership for Africa's Development (NEPAD), and U.S. FDA, to plan capacity building workshops in Kenya and South Africa, emphasizing the importance of harmonizing training curricula; and (3) in Southeast Asia providing preliminary suggestions for the Indonesian Ministry of Health's Standard Operating Procedure (SOP) for its medical device regulatory framework, aiming to streamline the approval process.

2.2 Non-COVID-19 Related Activities Activity Implementation Progress

GLOBAL

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

Activity #13 – Support for critical minerals standardization coordination

In March 2023, ISO/TMB and ISO Council approved and accepted the report of the Strategic Advisory Group (SAG) on Critical Minerals. The group's mandate was agreed as follows:

Undertake an analysis of existing and potential standardization work in the area of critical minerals from the point of initial extraction (mining and production of raw materials), and processing steps through to pre-cursor materials; and make recommendations to the TMB in this regard.

ANSI, as the U.S. representative to ISO and an active member of ISO/TMB and ISO Council, participated in the SAG. The SAG on Critical Minerals recently provided a report of its recommendations to the ISO/TMB, and in parallel, a new technical committee was established, ISO TC 345 on Specialty Metals and Minerals. In Year 5, the SA2 will support the work of the SAG on Critical Minerals and TC 345 through activities such as:

- Conducting awareness building to explore forming a U.S. mirror committee (TAG) to further bolster U.S. input and/or leadership in TC 345, thereby influencing outputs at the international level.
- With the input of the VTAG, support activities recommended by the SAG as next steps including dialogue with other ISO members in support of any new standards proposed or developed; training or awareness-building activities that would enable developing countries to participate in standards development for critical minerals.
- Coordinate within the U.S. stakeholder group including U.S. government agencies to align future work within ISO with U.S. strategy on critical minerals.

Implementation started in September 2023 where ANSI initiated the setup of a U.S. TAG to participate in the activities of ISO/TC 345 by:

- Selecting a US TAG chair, John Bonevich from NIST, and confirming he is able to perform the role;
- Creating the TAG website accessible to all US TAG members that will house all information

related to the work of TC 345 and the US TAG;
- Scheduling biweekly meetings starting in October 2023 with the US TAG chair to begin coordination and planning;
- Holding biweekly meetings with USAID to move the project forward;
- Identifying potential TAG members and informing them of the formation of the TAG;
- Working with the TAG chair to improve the outreach list.

AFRICA

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

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

Partner countries: Ghana, Uganda, and Zambia

Activity #3.2 – Conduct in-person or virtual interviews with Ministries, regulators, National Standards Bodies, utilities, private sector partners and civil society organizations

The CWSC continues targeted interviews based on recommendations from IAPMO in order to answer research questions #3 and #4 regarding any additional barriers from other sectors that are limiting NQI and workforce development efforts. For example, CWSC and IAPMO are in the process of setting up a meeting with a member of the private sector to determine whether there are any additional barriers to NQI that they experience beyond what we have identified. To date, very little has come up through interviews, however the team believes that by reengaging with the private sector members as mentioned above will allow for better answers and should help identify additional barriers that may be hindering NQI.

Please see CWSC's Q4 2022 Report for the list of stakeholders interviewed in Q4 2022.

Activity #3.3 – Incorporate findings from deskwork and interviews into comprehensive country-level reports

The CWSC has focused on reviewing feedback on the three Country Reports from IAPMO, USAID, and ANSI. It has begun drafting the Trend Report, which will be published on ANSI's Standards Alliance: Phase 2 website, under the resources section. In order for the information to be accessible to the public and ensure relevant stakeholders can digest the technical information shared in the report. As CWSC was analyzing the country-level reports for inclusion in the Trend Report, CWSC found many overlapping trends. Additionally, the three country level reports, while informative and comprehensive, were not designed to be public-facing, but rather internal resources for IAPMO and ANSI. However, significant parts of the country reports will be included as annexes to the Trend Report. The Trend Report provides more narrative and compares and contrasts the approaches taken by each country. The intention of the final country-level reports and Trend Report were discussed with IAPMO and ANSI, which both agreed that this approach would be better suited to support IAPMO's interests in the legal WASH framework across the three countries. It will also provide country-level stakeholders an opportunity to learn from their regional partners.

The CWSC anticipates using the education and engagement sessions as additional opportunities to validate

findings.

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

Partner country: Mozambique

In September 2023 the team organized a two-day capacity-building training in Maputo, which was hosted in collaboration with the National Institute for Normalization and Standards (INNOQ) and provided an opportunity for bioethanol energy and standards experts from Mozambique and the United States to share international best practices and policies for bioethanol standards development, both in the clean cooking and transportation sector.

Two-day capacity-building training in Maputo was hosted in collaboration with the National Institute for Normalization and Standards (INNOQ) and provided an opportunity for bioethanol energy and standards experts from Mozambique and the United States to share international best practices and policies for bioethanol standards development, both in the clean cooking and transportation sector. The workshop aimed at introducing the following points:

- Introduce bioethanol as an economic driver in line with the Economic Stimulus Package that includes biofuels blending goals
- Provide technical assistance and determine a pathway for adopting ASTM E3050
- Tour a clean cooking business for a first-hand look at implementation to inform policy makers, government, and private sector
- Build awareness and understanding of relevant international standards for bioethanol quality, safety, and management systems
- Discuss the adjacent sector impacts on health, environment, climate, and related socio-economic considerations
- Engage with members of relevant ministerial committees, the private sector, and standardization bodies to dialogue around the next steps for implementing appropriate regulatory frameworks

The workshop was designed to support the development of Mozambique's bioethanol economy through blending mandates and other related goals stated by the government and specific to the August 2022, Economic Acceleration Stimulus Package (PAE). It was incredibly synergistic that Pivot had submitted a concept note for a workshop in Mozambique prior to the launch of the PAE, and were then contacted by the US Department of Commerce in Mozambique to pursue ways of implementing the biofuels strategy. Pivot has been leading policy discussions with a group of stakeholders over the last year, which allowed us to structure the event with a greater awareness of dynamics in the country, and make connections that were beneficial to workshop implementation.

The final objective of this activity is to create a Clear pathway for adoption of ASTM E3050 leveraging this workshop. Indeed, there was discussion around the adoption of ASTM E3050 regarding bioethanol cooking fuel, by their national standards body, INNOQ. We reviewed the process at length during a working session, and they have started the process and are eager to adopt E3050 by November of this year. We encouraged them to simultaneously adopt standards for bioethanol and biodiesel blending for transportation and they have already requested 4 additional standards to pursue adoption for bioethanol blending.

INDO-PACIFIC

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

Activity #7 – Increase the Flow of WASH Services

Partner country: Indonesia

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

Since its publication, SNI 122:2022 is a voluntary standard. Until it is made mandatory by a ministry, PT IAPMO Group Indonesia is seeking to be appointed as the Product Certification Body recognized by BSN. IAPMO is in discussion with Indonesian manufacturers interested in certification to SNI 122:2022 in order to initiate that formal process.

IAPMO is in discussion with the Ministry of Industry and is awaiting data to review in order to prepare the Risk Impact Analysis (RIA) draft. Due to this, the completion of the RIA (originally expected in Q3 2023) will likely be delayed. Following the completion of the RIA and support from local manufacturers, IAPMO will initiate the proposal to make SNI 122:2022 mandatory to the Minister of Industry and BSN.

IAPMO continues to collaborate with the Indonesian Plumbing Association (APIN) to disseminate this standard and to continue educating manufacturers about the importance of compliance with this new standard to ensure the safety and performance of their products, as well as to make their products more competitive at the global market.

As reported on in Q2 2023, the PT IAPMO Group's faucet testing laboratory has full capabilities to test to SNI 122:2022. The lab's accreditation by KAN is still pending.

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

In Q3 2023, MDRC continued its efforts to advance GRP in medical technology regulatory frameworks through engagements at local, regional, and global levels. During meetings with stakeholders, including ministries of health, regulatory coordinating bodies, standards organizations, and regional trade associations, MDRC observed that the absence of strong legal foundations and the exclusive use of

regulations for pharmaceuticals and medical technology undermine harmonization and GRP. MDRC also highlighted that many regulatory bodies have limited dedicated staff for medical devices, emphasizing the importance of prioritizing training on reliance and regulatory convergence over resource-intensive processes such as dossier reviews, which can create medtech trade and health barriers.

In September 2023, MDRC attended the Management Committee Meeting of the IMDRF in Berlin, Germany. On the sidelines of the IMDRF, MDRC met with key stakeholders including the Global Medical Device Nomenclature (GMDN) Agency to provide an update on the 6-9 November AMDF continental trainings and explore how nomenclature guidelines can be included in the agenda. The MDRC also held multiple side meetings with the FDA and MDRC NRAs including PPB, SAHPRA and ANVISA, coordinating remaining 2023 MDRC workstream implementation.

During Q3, MDRC also continued to engage in regular coordination meetings with USAID and its related projects; the Medicines, Technologies, and Pharmaceutical Services (MTaPS) and Quality of Medicines Plus (PQM+). These coordination meetings present an opportunity for project teams to share learnings, identify priority outputs, and align on technical guidance. Going forward, USAID and these projects will continue to use the monthly meetings to increase coordination efforts and develop a common set of knowledge tools and reference guides.

Africa

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

Regional

In Q3 2023, MDRC focused on coordination efforts and capacity building in collaboration with U.S. and regional and continental stakeholders such as NEPAD. On 19 July, MDRC held a coordination call related to the USTDA/BCG project, which concentrates on planning MedTech and pharma regulatory training sessions in Kenya and South Africa. The aim was to ensure complementarity between USAID and USTDA projects. MDRC shared its plans to conduct hybrid training sessions in Kenya during the third week of August, primarily focusing on PPB but open to all relevant stakeholders interested in capacity building. MDRC also discussed upcoming continental trainings scheduled for November, emphasizing that the training curricula for both August and November sessions would be complementary. It was noted that SAHPRA executives from South Africa would be in the U.S. during 21-25 August and were tentatively scheduled to meet with the Center for Devices and Radiological Health (CDRH), making it unlikely for SAHPRA to attend the August MDRC trainings in person, although virtual participation was considered. MDRC agreed to share its training curriculum with the USTDA/BCG project, and both sides discussed the potential for a complementary visit with MDRC in Washington while SAHPRA was in the United States to meet with the FDA.

On 1 August, MDRC conducted a meeting with U.S. FDA to coordinate activities related to capacity building sessions. This included planning for the capacity building session in Nairobi as well as the MDRC-AMDF Capacity Building event scheduled for 6-9 November. The coordination aimed to ensure that these sessions are well-organized and aligned with the goals of enhancing regulatory capacity and knowledge sharing in the medical device sector. The collaboration between MDRC and U.S. FDA highlights their joint efforts in promoting regulatory excellence and fostering partnerships to strengthen regulatory systems in the healthcare industry.

Finally, MDRC continued its coordination with various USG entities providing capacity building and aid funding to Africa. With USAID, this included the monthly calls with the USAID Global Health project teams of PQM+ and MTaPS together with the U.S. Food and Drug Administration – Center for Devices and Radiological Health (FDA/CDRH). With the USTDA, this now includes MDRC coordination with three different USAID project teams established under the new USTDA Africa Health Coalition, led by three different USTDA contractors including the Corporate Council on Africa (CCA), the Boston Consulting Group (BCG) and the Webster Group, all three now interfacing with PPB, SAPHRA and other regional National Regulatory Authorities (NRAs).

Ghana

During the AMDF capacity building workshop on 6-9 November, MDRC will sponsor NRAs from project countries, Ghana, to maximize attendance across project country NRAs.

Kenya

In Kenya during Q3, MDRC engaged in several crucial activities to enhance medical device regulatory capacity and cooperation to build regulatory capacity, foster collaboration, and promote use of international standards in Kenya's medical device sector. On 7 and 14 July, MDRC held meetings with the Kenya Pharmacy and Poisons Board (PPB) to refine the training agenda for August. The training curriculum was discussed, with a focus on distinguishing between medicines and medical devices. The training dates were rescheduled to 22-24 August, and speakers and facilitators were selected for the PPB session.

The 3-day capacity-building workshop involved multiple participants, including representatives from the private sector. The event covered topics related to medical devices, in vitro diagnostics, risk classifications, and global standards. It also included panel discussions on alignment in risk classification and the principles of safety and performance in the medical device sector. The workshop convened over 110 unique participants over three days of trainings and included representatives from WHO, four NRAs, the U.S. National Institute of Standards and Technology (NIST), the Association for the Advancement of Medical Instrumentation (AAMI), and the private sector, totaling engagement of 10 countries through a combination of in-person and virtual attendance. Singapore's Health Sciences Authority (HAS) (in-person), U.S. FDA, Australia's Therapeutic Goods Administration (TGA), Brazil's ANVISA representatives engaged in panel discussions and presentations covering critical topics included in the Training Curriculum jointly developed by U.S. FDA and MDRC.

Following the workshop, MDRC met with Mr. Kibet Kisorio, a legal representative from PPB, to address shortcomings in PPB's guidelines for developing regulations. They discussed areas of misalignment and the need for technical support during the review process. As a result, PPB agreed that MDRC will review the Standard Operating Procedure on Public Consultation and the Guidelines for Draft and Review of Regulatory Instrument to provide support on a gap analysis and recommendation for GRP improvements.

MDRC also had follow up conversations with PPB to convey recommendations for refining technical guidelines to align with international standards and to discuss opportunities and challenges related to international standards utilization. MDRC emphasized the importance of further engagement with both PPB and industry to enhance participation in technical committees and improve Pre-Export Verification of Conformity (PVoC).

MDRC and PPB also discussed the possibility of another training session in September, focusing on nomenclature in coordination with the Global Medical Device Nomenclature (GMDN). GMDN proposed a two-day agenda in September, awaiting confirmation from PPB on dates and logistics. This discussion was part of the broader initiative to build regulatory capacity in Kenya. It was later agreed to consider potentially including this topic within the agenda of the AMDF capacity building event in November.

While on the ground in Kenya, MDRC met with the African Organisation for Standardisation (ARSO), who participated in the workshop. ARSO recognized the need to increase knowledge of GRP and proposed a training session to address this need. They also sought feedback from committee members to identify additional capacity-building needs.

In September, MDRC held post-workshop meetings with the Medical Technology Industry Association of Kenya (MEDAK) and the Kenya Bureau of Standards (KEBS). Mecomed expressed interest in assisting MEDAK organize a training session on GRPs and TBT that builds upon the primary results from the Kenya PPB capacity building in August and schedule the next training sessions. MDRC urged MEDAK and other affiliated entities to join technical committees, ensuing their active participation in standards development. For the next step, members are encouraged to contribute proposal and recommendations for inclusion in the draft agenda of the upcoming November training.

South Africa

During Q3, MDRC planned for upcoming Q4 trainings in South Africa. MDRC held meetings with SAMED, during which the parties discussed the current regulatory environment in South Africa, exchanged updates on the planned capacity-building workshop in Kenya, deliberated on the agenda for the upcoming meeting with the SAHPRA in Washington, D.C., and provided an update on the status of the MDRC-AMDF meeting scheduled for 6-9 November. These discussions underlined the importance of collaboration between regulatory authorities and industry stakeholders in shaping the regulatory landscape.

In August, MDRC engaged in a meeting with SAHPRA as part of USTDA-organized meetings at AdvaMed in Washington, D.C. During this meeting, MDRC presented an overview of the MDRC project and its multifaceted objectives, which encompass foundational GRP and the development and utilization of international standards for medical technologies. A key concern raised by SAHPRA was the rules governing consultations with the medical device industry, emphasizing the necessity of aligning on common health and medical objectives. Moreover, SAHPRA expressed a need for insights into how international standards might impact local medical device manufacturers. Discussions also delved into the complex dynamics of treaty obligations assumed by the South African government over domestic legislation and regulations, including considerations related to the WTO/TBT agreement. The role of the Department of Trade and Industry (DTI) in resolving conflicts between the legislature, SAHPRA, and South Africa's trading partners was a significant point of discussion.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

Indonesia:

In Q3, MDRC initiated a comprehensive review of the MOH's existing SOP for medical device regulatory approval. Preliminary comments and suggestions, aligned with international best practices, were provided

in a draft document. MOH undertook a review of these suggestions and queries, with plans to arrange a follow-up meeting in August. The ensuing comprehensive response from MDRC will serve as the foundation for a revised SOP, aiming to enhance and streamline the medical device regulatory approval process in Indonesia.

Throughout the quarter, MDRC conducted virtual meetings with representatives from Indonesia's MOH. Discussion centered on the prerequisites for future technical assistance, particularly in light of the recently introduced Omnibus Law. This legislation presented an opportune moment to formalize the SOP for medical device regulation, ensuring its alignment with the omnibus law's provisions. MOH expressed the desire for technical assistance, proposing the inclusion of an embedded consultant within MOH. This consultant would play a pivotal role in facilitating the effective implementation of the SOP, ensuring its compliance with the new law. The meeting also involved the presentation of the "Permenkes" document, drafted by the MOH, to be translated for further examination.

On 31 August, MDRC engaged in a meeting with the USAID Jakarta team to discuss the evolving strategy in response to Professor Laksono's request for an embedded consultant. Given the project's timeline constraints, it was collectively acknowledged that this long-term objective might not be feasible during Phase 2 of the project. As an alternative strategy, the team proposed the translation and comprehensive review of specific articles within the omnibus law pertaining to medical devices. The articles identified for translation and review were crucial for the medical device regulatory landscape and compliance. This review aims to align the provisions of the omnibus law with the existing "Permenkes" regulation, ultimately culminating in a revised SOP. This revised SOP will empower MOH with a regulatory framework that incorporates the new law's articles, enhancing the likelihood of effective compliance.

Additionally, MDRC initiated discussions with a group of medical device experts in Indonesia, introduced by Professor Laksono. This introductory meeting allowed the MDRC team to present the project and its activities to the expert group, which included prominent individuals in the medical device field. While this was a preliminary meeting, there is potential for future collaboration between the expert group and MDRC, reflecting the project's commitment to engaging with local stakeholders to strengthen Indonesia's medical device regulatory capacity.

Latin America

Activity #12.11 – The Coalition will lead regional MDRC project efforts, convene stakeholders for meetings/trainings, and provide capacity-building resources.

The Coalition led regional and local project efforts throughout Q3 2023. An overview meetings and trainings may be found in Section 2.1 Progress Narrative and Section 3 Stakeholder Participation and Involvement. An overview of the major developments is listed below:

- Led the execution of trainings in Colombia to advance GRP implementation. The trainings focused on citizen participation in the regulatory agenda and legal techniques for writing regulatory texts.
- MDRC provided capacity building resources through the Coalition website https://www.interamericancoalition-medtech.org/regulatory-convergence/.
- Mexico: 7 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. MDRC continued efforts to develop and approve checklists for implementing GRP in key governmental bodies. MDRC advanced several workstreams.

- Peru: 1 formal meeting with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.
- Colombia: 21 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development. See Activity 12.24 for more info.
- Brazil: 3 formal meetings with Tier One and Two stakeholders, not including regular correspondence, informal conversations, or collaboration in resource development.

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

During Q3, MDRC planned for the upcoming PAHO External Stakeholders Sessions and sideline engagements led by the Coalition that will take place 10-13 October in El Salvador. The session will engage local stakeholders from all four Latin American project countries and advance project objectives with respect to Emergency Use Authorization (EUA) and reliance. MDRC confirmed the participation of several government stakeholders, including Health Canada and U.S. FDA.

MDRC also continued coordination efforts with the U.S. FDA Latin America office and discussed plans for MDRC to share the registration link for the AMDF capacity building workshops in November with local NRAs in the region, including COFEPRIS. MDRC and U.S. FDA co-developed a program on advanced GRP elements such as regulatory impact assessment and effectives, which will be delivered in Q4.

Brazil

In Brazil, MDRC had several significant engagements with stakeholders including ANVISA, the Ministry of Industry and Development, and the National Institute of Metrology, Standardization and Industrial Quality (INMETRO) focused on regulatory cooperation and international agreements.

On 8 August, MDRC conducted a meeting with ANVISA to review international agreements, notably the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) (WHO/TBT) and the U.S.-Brazil ATEC Protocol. The discussions addressed Mthe potential negotiation of a sectorial annex on medical devices between Brazil and the United States, ANVISA's participation in the AdvaMed 2023 MedTech conference, and ANVISA’s role in a workshop during the global Medical Device Single Audit Program (MDSAP) week. Key outcomes included ANVISA's commitment to review MDRC topics for potential inclusion in the ATEC sectorial annex and endorsement of a workshop on medical device conformity assessment. However, challenges were acknowledged, such as internal alignment with ANVISA's international department and staff bandwidth constraints.

On 25 August, MDRC met with the Brazilian Embassy in Kenya. The meeting introduced the MDRC project, and participants discussed ANVISA's participation in the upcoming August capacity-building workshop in Nairobi, Kenya. The Brazilian Ambassador expressed interest in Brazil's health benchmarking and committed to supporting MDRC in future events, underscoring MDRC's role in advancing South-South alliances and sharing best practices among project countries. These engagements highlight Brazil's active involvement in international agreements, collaborative regulatory efforts, and capacity-building initiatives pertaining to medical devices. ANVISA's engagement with international partners plays a pivotal role in advancing regulatory practices within the country.

Furthermore, on 29 August, MDRC engaged with the Ministry of Industry and Development – Division of Competitiveness and Regulatory Practices (MDIC/SCPR) in Brazil. The focus was on shared regulatory responsibilities between ANVISA and INMETRO in medical device conformity assessment procedures, guided by a technical cooperation agreement. Discussions also extended to potential participation in an upcoming public consultation regarding quality infrastructure. An action plan was introduced, outlining activities for the remainder of 2023, including an International Experience Exchange Workshop, Internal Regulatory Alignment, Subsidy Evaluation, and the revision of INMETRO's Good Regulatory Practices Manual. The action plan for the second half of 2023 encompasses four key segments:

- **International Experience Exchange Workshop**: Scheduled for 24 October 2023, in Brasilia, this workshop focuses on medical device regulatory exchanges between the U.S. and Brazil, particularly conformity assessment programs.
- **Internal Regulatory Alignment**: INMETRO aims to enhance internal regulatory alignment by 20 October 2023, utilizing a checklist to promote transparency and international compliance in creating and reviewing technical and conformity assessment regulations.
- **Subsidy Taking**: INMETRO plans to evaluate the public consultation rationale within the existing plan, exploring potential contributions from the Coalition.
- **INMETRO Good Regulatory Practices Manual**: INMETRO is assessing contributions to revise its Regulatory Practices Manual in alignment with the Ministry's strategic development, with feedback expected by 1 October 2023.

Colombia

In Q3 2023, MDRC made substantial advancements in its collaborative efforts with local Colombian stakeholders to enhance regulatory practices, promote international alignment, and foster collaboration with government entities to streamline processes and achieve a stronger regulatory environment. In July, MDRC proposed work plans to the Ministry of Commerce, Ministry of Health, INVIMA and DNP in order to continue strengthening the implementation of the regulatory improvement policy with a focus on technical regulations.

In August, MDRC held discussions with the Ministry of Commerce, focusing on designing a guideline to address TBT Agreement commitment within the regulatory processes for medical device. The proposed guideline aimed to provide clarity on the application of the term "administrative applications" within technical regulations, a key aspect of the TBT agreement. The guideline is based on the TBT agreement's technical regulation definitions and WTO's stances in disputes related to the definition of Technical Regulation in Annex 1 of the TBT Agreement. The Ministry of Commerce expressed interest in reviewing technical regulation guides from countries such as the United States and provided feedback on the guideline prepared by MDRC in September. Additionally, MDRC suggested creating a checklist outlining the steps entities should follow to regulate a technical standard compliant with the TBT agreement, which would apply to all national entities, including the health sector.

Simultaneously, MDRC engaged with DNP to support the alignment of regulatory public policy with international standards, particularly in technical regulations. The proposal included activities to strengthen the implementation of GRP through the development of a procedure to be included in the Integrated Planning and Management Model (MIPG) that would apply to all national government entities and local governments. This procedure is modeled on the procedure that was previously approved by the Ministry of Health and recognized by the DNP in the national contest for GRPs. MDRC also engaged with INVIMA

to advise on the creation of a process for technical regulation evaluation, emphasizing institutional capacity and international references. MDRC shared the proposal and is waiting to receive feedback.

In September, MDRC intensified its efforts with a series of follow-up meetings and presentations with government stakeholders. The Ministry of Commerce agreed to hold weekly meetings for the expedited review of the proposed guidance and checklist. DNP also confirmed weekly meetings to discuss the methodology for approving a procedure in November. Finally, the Ministry of Health agreed to hold weekly meetings after approving MDRC's proposed workplan so that the group could enhance stakeholder participation and tools included in the procedure.

MDRC also collaborated with DNP to review an operational guide for policy updates, which will be linked to the procedure proposed. MDRC emphasized that the guide should incorporate explicit mention of the technical regulations and their alignment with the TBT Agreement, reference the guide MDRC is developing with the Ministry of Commerce, and include entities like INVIMA for policy compliance. The steps included in the procedure for regularly improvement will ensure that actions outlined in the guide can be accomplished. highlight that everything indicated therein can be accomplished with the steps listed in the procedure for regulatory improvement.

MDRC also held a meeting with a point of contact for Colombia's single public consultation system (SUCOP), a digital platform introduced in May 2018 that centralizes stakeholder engagement practices across all government entities. MDRC shared a proposal for the new stakeholder participation format co-developed by MDRC and the Ministry of Health. DNP accepted the proposal for its adoption and will review the budget for the development of the technological platform to determine whether the new format can be implemented this year.

Mexico

In Q3, MDRC made significant progress in its engagement with COFEPRIS in coordination with partners such as U.S. FDA and Dorantes Advisors. In July, MDRC had a meeting with COFEPRIS, where COFEPRIS expressed concerns about feedback received from stakeholders regarding NOM-241. Despite their efforts to address concerns through notices and updates, issues regarding to nonalignment with international standards remain. MDRC acknowledged COFEPRIS's actions but expressed concerns about the implementation of internal criteria and the legal weight of certain notices. Legal analysis developed by MDRC on alternatives to address concerns were discussed. Subsequently, COFEPRIS agreed to schedule a meeting with their legal department to review the conclusions.

In August, COFEPRIS shared plans to publish the "Strategy for Regulatory Certainty for MDs" and submit the application to become a member of MDSAP. After several delays, the publication of the "Strategy for Regulatory Certainty for MDs" was rescheduled to coincide with the export only manufacturers event in Tijuana, Baja California on 12 October. MDRC and COFEPRIS also discussed the Extensive Equivalent Agreement, which COFEPRIS has committed to publishing in the upcoming months. MDRC emphasized the importance of involving the COFEPRIS GRP Committee in this process and offered to develop a legal analysis of the GRP domestic and legal obligations which are applicable to this type of instrument. Additionally, MDRC offered to conduct a refresher training course for the committee members. MDRC delivered the legal analysis, which COFEPRIS shared with their legal department, and also reminded COFEPRIS of commitments made in March 2023, including the inclusion of NOM-241 in the 2024 Quality Infrastructure Program regulatory agenda and the issuance of legally-based interpretation criteria.

During Q3 meetings, the need for data on monthly submissions via equivalence agreements was discussed, along with the growing backlog trend. COFEPRIS expressed interest in a training session on reliance experiences with case studies from other countries. MDRC offered to share access to workshop materials once uploaded to the MDRC website. Participants also discussed the possibility of industry experts in Process Engineering assisting with process-related issues contributing to the backlog.

To advance progress on NOM-241, MDRC also met with the U.S. FDA Latin America Office and presented its analysis of NOM-241, focusing on the legal weaknesses of the "Circulares." MDRC proposed including these "Circulares" in the 2024 NQI. During the discussion, a joint webinar on GRP was proposed, with the FDA offering to collaborate. This webinar would cover topics like public comments management and case studies. The plan was to organize this webinar in the coming months.

Lastly, in September, MDRC extended an invitation to COFEPRIS to present on Emergency Use Authorizations at the MDRC Session on the sidelines of the PAHO Open Stakeholders Session. COFEPRIS confirmed their in-person participation, marking the first time COFEPRIS has confirmed in-person participation under SA2. COFEPRIS also confirmed the formal submission of their application to become an Affiliate Member of MDSAP, which is a major milestone achieved through the years-long joint effort by COFEPRIS – U.S. FDA and MDRC.

Peru

On 10-11 August, MDRC participated in the 16th Conference on Good Regulatory Practices held as a part of the U.S.-hosted Asia-Pacific Economic Cooperation (APEC) SOM3 meetings in Seattle, WA. USTR has leveraged the U.S. 2023 hosting of APEC to advance a new APEC GRP Blueprint. MDRC has been coordinating with USTR in the development of the draft Blueprint and APEC to ensure alignment of MDRC Tier 1 activities with related USG and APEC efforts that impact MDRC Tier 1 work in the Americas and Southeast Asia regionals as well as with MDRC countries including Peru, Mexico and Indonesia. Key speakers in the Conference included USTR, the Office of Information and Regulatory Affairs (OIRA), OECD as well as the Inter-American Development Bank (IDB) in line with MDRC encouragement for GRP coordination between APEC and the IDB.

Steven Bipes of AdvaMed, Renee Hancher of USTR, Emily Espoo of the Department of Commerce International Trade Administration (DOC/ITA), and Nathan Frey of the RSS Group supporting U.S. Support for Economic Growth in Asia (USSEGA), held a side meeting with the Peruvian delegation to the Conference including Clara Vasquez-Caicedo Nogales, the Technical Advisor for Good Regulatory Practices to the Presidency of the Council of Ministers (PCM) and Rocio Barreda Santos of Peru's Ministry of International Trade and Tourism (MINCETUR) on advancement of GRP implementation in Peru and where MDRC efforts might best complement Peruvian efforts. It was noted that a significant portion of the current PCM staff is sponsored by the IDB under a program ending in 2023 and there are questions as to how the government of Peru plans to maintain its GRP efforts thereafter with impact on how GOP may absorb MDRC Tier 1 support.

2.4 Implementation Challenges

Activity #3 – Research on WASH-related product standards and their reference in law, regulation, and policy

The CWSC concluded that Research Questions (RQ) #1 and #2 fully cover the relationship between law and NQI. We did not find any unique, or additional limitations as expressed as part of RQ#3. While, that is the case, we have comprehensively addressed how law governs WASH NQI.

CWSC plans to host one combined education and engagement session for the three countries. Given that the Trend Report will be the published report, and the comparison is an important feature of that report, we believe it is important to have a session that covers all three countries, and that the audience includes representatives from all three countries.

The CWSC met with PAZA, the Plumbers Association of Zambia. They provided important feedback on workforce development. However, we have not been able to identify similar groups in the other countries. Therefore, the broader takeaway will be that this should be an area of development.

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Government Mobilization

Mexico

In Q3 2023, MDRC experienced difficulties in making progress with its workstreams with COFEPRIS since COFEPRIS through the Commission of Sanitary Promotion published Oficio No. COFEPRIS-CFS-214-2023 which excludes the manufacturers under the Manufacturing, Maquila and Export Services Industries Program (IMMEX) from the scope of NOM-241. In May, MDRC along with the Mexican Association of Innovative Industries of Medical Devices (AMID), the medical device committees of the National Chamber of the Pharmaceutical Industry (CANIFARMA), INDEX and global companies' representatives met with the Ministry of Economy. The Minister proposed the creation of a taskforce including Ministry representatives, COFEPRIS, and representatives of the private sector to identify next steps for a definite solution. The taskforce has not yet been convened.

In Q3, drafted the "Strategy for Regulatory Certainty for MDs," which includes inputs and recommendations from MDRC. If COFEPRIS can publish and implement this document immediately, and in a manner consistent with Mexico's domestic and international treaty obligations on GRPs – which have been the subject of U.S.-Mexico capacity building under the MDRC – this should assist COFEPRIS in taking material action toward resolving the issues regarding nonalignment with international standards and trade bottlenecks. This document is awaiting publication.

During Q3, MDRC reminded COFEPRIS of commitments made in March 2023, including the inclusion of NOM-241 in the 2024 (NQI) regulatory agenda and the issuance of legally-based interpretation criteria. To include NOM-241 for formal review within the 2024NQI, as has been committed to by COFEPRIS, this must be submitted by October 2023 in order to fulfill the legal requirements.

WHO MedTech Guidance

MDRC continues to include the WHO and its international benchmark guidance for Medical Device National Regulatory Authorities (MD NRAs) in programming with project country NRAs. However, MDRC is of the assessment that a number of WHO recommendations and practices work at cross-purposes to MDRC efforts to build NRA capacities as well as guidance developed by the WHO itself as well as the IMDRF, FDA/CDRH, WTO and the WHO.

In Q3 2023, project partners, such as the FDA/CDRH, agreed with these concerns directly to the WHO. During coordination calls with USAID and project teams, MDRC discussed NRAs' reliance on WHO, especially in LMICs, and how inappropriate provisions of the Global Benchmarking Tool Plus (GBT+) and lack of GRP references in WHO guidance documents can hinder MDRC's ability to realize its full project objectives. USAID and FDA shared that they will seek additional opportunities to engage with WHO on pilot tools and to provide feedback on GBT+, noting that support from MDRC and other project teams will be beneficial.

As MDRC outlined in-depth three examples of inappropriate WHO practices in the Q2 2022 Report, they are briefly enumerated below:

1) Inappropriate Provisions of the WHO Global Benchmarking Tool Plus (GBT+)
2) The WHO does not follow its own guidance on Good Regulatory Practices in the development and publishing of WTO guidance documents.
3) Lack of adherence to the WHO Global Model Regulatory Framework (GMRF) stepwise approach.

MDRC has recommended that its U.S. Government partners (such as the HHS, FDA, and USAID) consider establishing a dialogue with the WHO to address these points in bilateral or multilateral fora. The MDRC has also recommended the GMTA consider a parallel dialogue with the WHO with a view to aligning international aid and capacity building approaches with NRAs.

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

The approval and invitation process were cumbersome, and delayed the sending out of official letters to top government positions, as well as general invitations. Due to the USAID Mission presence in Mozambique, protocol dictated that they either send the invitations from their office, or decline and allow ANSI/Pivot to send them out. The Mission response time was such that it did not allow for much window to get invitations out or provide follow-up. That being said, we did have good attendance, but we could have potentially had more engagement from government officials if the communication had occurred sooner.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
12	12.5	Kenya	PPB for Capacity-Building Workshop	22 – 24 August	Day-1 119 attendees 77 female, 42 male

					(58 private sector) Day-2 96 attendees 58 female, 38 male (26 private sector) Day-3 99 attendees 62 female, 37 male (29 private sector)
14	N/A	Mozambique	Standards for Bioethanol Household Energy Workshop	September 18-24, 2023	46 total participants: Private sector: 27 Female participants: 29

4. RESULTS ACHIEVED

Performance Indicator #2: Number of trainings conducted about the value of using their national quality infrastructure

Under this reporting period for this performance indicator there are a total of **2** trainings to report. A breakdown of the different workshops is presented below by activity.[1]

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

For Q3 2023, MDRC set a target of **1** workshop under this target was achieved in hosting the capacity-building workshops in Nairobi, Kenya with PPB.

For Q4 2023, MDRC sets a target of **4** workshop under this indicator.

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

[1] Activities not mentioned under this section did not select it for their implementation.

The target for this activity was to hold **1** training event during this reporting quarter. With the organization of the workshop in Maputo in September 2023 this target was then reached.

This marked the last event under this activity and as such there are no other targets to set.

Performance Indicator #9: Number of workshop/reserve trade mission participants (Related to Technical Barriers to Trade awareness)

Under this reporting period for this performance indicator there were a total of **1** workshop to report with an objective of **75** participants. A breakdown of the different participants in said workshops is presented below by activity.[2]

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

For Q3 2023, MDRC executed 1 training on GRPs and Medical Device Regulation. The team had a target of **75** participants; which it exceeded counting with approximately 314 participants in the training. These trainings are essential to building good regulatory capacities and addressing barriers to trade by:

- Delivering high-level presentations on GRP policy implementation at both Tiers One and Two;
- Emphasizing the role of GRP in both recovery from COVID-19 and reducing barriers to trade;
- Participating in in-depth examinations of workstreams to implement GRPs, including timelines and plans for future implementation;
- Exploring efforts to document GRP implementation within pilot project regulatory agencies; and
- Facilitating long-term GRP collaboration among the project countries.

For Q4 2023, MDRC sets a target of **100** participants under this indicator.

5. LESSONS LEARNED

Activity #12 – COVID-19 Medical Device Regulatory Convergence Project (MDRC)

The project team continues to incorporate lessons learned on hybrid in-person/virtual engagements with stakeholders. Learning from the execution of the events alongside the June 2022 Summit of the Americas, MDRC organized both virtual and in-person trainings in Q3 2023. Scheduling MDRC programming in conjunction with other major events and multilateral forums per requests from the FDA and MDRC NRAs has significantly facilitated MDRC advancement.

The project team continues to utilize its online capacity-building and digital resource capabilities to extend programming to a large virtual audience. While in-person training is extremely effective, most participants of MDRC trainings remain virtual. MDRC's virtual platform and Zoom licenses are critical to reaching those participants and offering simultaneous language interpretation for both in-person and virtual

[2] *Idem*

attendees. These learnings are increasingly critical in the effective execution of capacity building. Identifying the appropriate possible balance between theorical, hand-on trainings and open dialogue guided sessions is critical while planning future capacity building events, to maximize learning opportunities.

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

It could be helpful to be in touch with the USAID Mission 3-6 months in advance so that they are aware of the project and can state early on their level of involvement, if they are present in the target geography. It would also be key to stay in close contact with INNOQ so as to initiate more momentum for the adoption of the ASTM E 3050 Standard.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity #	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
12	12.5	South Africa		SAHPRA-MDRC training sessions with medical device NRAs utilizing a curriculum developed by FDA and GMTA.	12-14 November	Hybrid	Yes
12	12.6	Africa		MDRC-AMDF continental trainings	6-9 November	Hybrid	Yes
12	12.16	Mexico		GRP Training – Private Sector	October 5	Hybrid	No
12	12.16	Latin America		External Stakeholders Session, San Salvador, El Salvador	October 10	Hybrid	No
12	12.16	Latin America		Open Stakeholders Session – Joint PAHO – MDRC, San Salvador, El Salvador	October 11	Hybrid	No
12	12.16	Latin America		MDRC – Coalition Session, San Salvador, El Salvador	October 12	Hybrid	No
12	12.16	Latin America		Regional GRP Training	November 14	Hybrid	No
12	12.16	Peru		Capacity Building on Key Topics	November - TBD	Hybrid	No
12	12.16	Mexico		Stability Studies for Medical Devices	November 30	Hybrid	No
15	15.1	CDI		Roundtable 1 on successful experiences and models of national policies	November 2023	Hybrid	No