Standards Alliance: Phase 2

Quarterly Report

Q2 April 1st- June 30th 2023

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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, Ghana, Kenya, South Africa, Zambia, West Africa (regional), Indo-Pacific (regional)
Reporting Period:	Q2 April 1st- June 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 second quarter of 2023 continued with the implementation of activities under the approved subawards, and also saw the closing of some programs after they reached the completion of their workplan. The ASTM subaward held an in-person Study Tour in Denver, CO in conjunction with ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants. The Study Tour invited West African key stakeholders to continue to promote and solidify the work the project has done around petroleum standards harmonization in the region, facilitating cross border trade with the partner countries. Additionally, the MDRC program during this quarter has increased the implementation of its program in Africa having first jointly created global medical device curriculum approved by local industry and government; the curriculum marks a significant program output and will be a Global Medical Technology Alliance (GMTA) and International Medical Device Regulators Forum (IMDRF) contribution.

2.2. Non-COVID-19 Related Activities Activity Implementation Progress

AFRICA

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

Activity #1 – Economic Community of West African States (ECOWAS) Clean Renewable Fuels Workshops

Partner countries: West Africa, Mozambique

As detailed in previous reports this activity closed its implementation before the beginning of Q2 2023. However, its success was leveraged when Pivot submitted a new concept note for biofuel training, this time in Mozambique.

During this reporting period this new activity has received Mission concurrence from USAID in Maputo and will be preparing implementation under the following quarters.

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 regarding any additional barriers from other sectors that are limiting NQI and workforce development efforts. To date, very little has come up through their interviews.

The CWSC has spoken with IAPMO about additional stakeholders to interview. Thus far, CWSC interviewed PAZA, the Plumbers Association of Zambia. CWSC is working to set up a meeting with LIXIL, a global manufacturer of plumbing products. In these interviews CWSC will ask if there are additional barriers to NQI that they experience beyond what it has identified.

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 completed three draft reports for Ghana, Uganda, and Zambia. As part of this, the reports have undergone two revisions from ANSI and from IAPMO. The draft reports have now been shared with the USAID offices in each country for their review and comment.

Furthermore, CWSC will complete a draft Trend Report now that the country level reports have been developed.

Activity #8 – Utility Management Standards Training for water sector utilities

Partner countries: Lesotho, Malawi, and Zambia

Activity #8.3 – Conduct training with participants from Zambia, Malawi, and Lesotho water utilities

Virtual workshops were conducted in September 2022 and January 2023, with monthly follow-up/check-in calls in October, November, February, and March completed.

AWWA completed delivery of the third and final workshop in Africa which was held in-person in Livingstone, Zambia, on April 25th and 26th at the Protea Hotel Livingstone. The workshop included a full day of classroom instruction on the 25th, a tour of the nearby Southern Water and Sanitation Company utility's treatment plant on the morning of the 26th, and final classroom training and recognition of participants in the afternoon of the 26th.

Overall, the workshops were effective in introducing the utilities to the AWWA series of management standards. It is clear that the utilities want to strive for better service delivery to their customers and are lacking technical expertise as well as funding to do so. A notable engagement from the workshop was the worksheet sessions where participants worked in their utility group to choose management issues their utilities are facing. They discussed their issues as a group and then received direct advice from the facilitators and their peers on how to better manage their utility in accordance with the AWWA standards. Throughout the workshop, utilities were problem solving with each other, sharing information and were eager to keep in touch to assist each other.

AWWA and ROCKBlue recommend the following next steps in order to continue the momentum they have built with the utilities:

- **Continue Local Support:** First year efforts set the stage for a sustainable user group to assemble periodically to discuss specific standards, share best practices, write articles, and give presentations in subsequent years. Workshop participants were encouraged to participate in locally organized follow-up group calls after the workshops ended, with support from AWWA staff. The organization of this needs to be set up and manage. ROCKBlue, ANSI and AWWA should have a brainstorming session to specify what is necessary to sustain the benefits of the work conducted thus far. In the meantime, to support the participants with access to financing options, ROCKBlue organized and conducted an additional hour-long training regarding ROCKBlue's Access to Capital, Oversight, and Reporting Nexus (ACORN) program for participants to apply on May 24, 2023.

- **USAID adding funding to support implementing the standards:** As Kan Oberoi (one of the trainers) expressed, additional funding for this effort will greatly increase the likelihood of the African water utilities to benefit from applying the standards in their day-to-day work. Additional funding would allow AWWA's trainers and other US water industry specialists to advise the utilities starting with doing a gap analysis on-site at each utility for three days focused on water production and water distribution. The advisors would share their knowledge to assist the utilities

to determine action plans for making improvements. With these plans in place, AWWA's advisors would have virtual follow-up meetings with the utilities, advising them on courses of action, and providing them technical materials as needed. (Kan, David and Ken offered to be volunteer advisors. Other senior people from the US water sector undoubtedly will also have an interest in helping African water utilities. ROCKBlue also suggests promoting gender diversity within the instructors as this was lacking.) ROCKBlue would organize and coordinate the work and its Local Representatives and Utility Specialists would serve as extension agents on-the-ground for the advisors. ROCKBlue has been using this approach to support improvements in our partner water utilities for several years and has become a model for this type of assistance.

- **AWWA/ROCKBlue support for networking and cross-learning in implementing standards:** The participants expressed interest in having opportunities to learn both from each other with support from the AWWA specialists. ROCKBlue could facilitate virtual meetings for the utilities to share experiences as they implement the standards. These meetings can serve as a vehicle for the AWWA specialists to be a resource for the implementation of actions after the gap analysis mentioned above.

- **AWWA/ROCKBlue assisting Lilongwe Water Board to implement sewer and wastewater treatment standards:** Lilongwe Water Board has requested technical support for improving the performance of the sewer system and wastewater treatment plant infrastructure transferred from the city council in June 2023. A World Bank financed US$19 million program is well underway for sewerage rehabilitation and expansion, installation of 5,000 sewer connections, rehabbing and upgrading the Kauma sewerage treatment plant, among other measures. ROCKBlue could facilitate virtual meetings for AWWA's specialist(s) to be volunteer mentors to LWB in using the respective standards as a tool for this support.

This activity is now complete. Final reporting can be expected by Q4 2023.

Development Objective #2: Private sector actively participates in countries' national quality infrastructure

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

Partner countries: West Africa

Activity #5.6 – Conduct regular web and in-person conferences with working groups.

During Q2, much time was spent planning and executing a 5.5-day Study Tour in the U.S. for eight focal points. The Study Tour was successfully held in Denver, Colorado June 24-29, 2023. At the end of the Study Tour, a debriefing session was held to capture lessons learned and success stories from the 3-year project. As mentioned above the Study Tour took place in parallel with ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants.

During the duration of the Technical Committee, the designated project focal points came together to discuss applicable ASTM and API standards and testing protocols all the while attending key sessions of

the Technical Committee such as Standards Writing, Proficiency Testing, Statistical Quality Control, Recycled products standards, and Official Voter Registration. The study tour also included site visits to Peak Petroleum where the project focal points inspected various testing equipment, witnessed practical demonstrations, and spoke with lab technicians about testing method challenges for petroleum products here in the US.

The focal points were joined by visiting experts from Angola, Togo, and Kenya as well, underlining the strong buy in from regional stakeholders to work on Petroleum Harmonization.
The focal points were able to witness the ASTM International standards development process firsthand. The active engagement of members throughout the standard-setting process is central to ensure their quality and relevance; and help them build more success stories to report to the SA2 program before its closing in 2026.

With the successful implementation of the Study Tour, this activity is now complete. Final reporting can be expected by Q4 2023.

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.

Currently, SNI 122:2022 is considered 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 currently in discussion with Indonesian manufacturers interested in certification to SNI 122:2022 in order to initiate that formal process.

As reported last quarter the PT IAPMO Group's faucet testing laboratory now has full capabilities to test to SNI 122:2022. The lab's accreditation by KAN is still pending. In informal discussions with BSN, the agency indicated to PT IAPMO that the preparation of the RIA as indicated on the schedule may be delayed. PT IAPMO is working to obtain more details.

LATIN AMERICA

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

Activity #9 – Community Water Systems – Standards for safety and risk management

Partner country: Brazil/ Morocco

As mentioned in previous reports this activity has been completed. However, its success is currently being leveraged to develop a new activity with NSF to work on water bottle certification in Senegal. The country has expressed strong interest in the activity and a Concept Note is currently being prepared with plans of being shared with USAID under Q3 2023.

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

Activity #12.1 – The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (the Coalition) will lead in implementing and managing a dedicated COVID-19 Medical Device work stream at the global level on behalf of the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance (GDA) working in conjunction with the IMDRF.

The Coalition continued advancing MDRC objectives in its leadership of an International Center for Emergency Regulatory Response (ICERR) in the form of a dedicated COVID-19 Medical Device workstream of the GMTA/GDA. This workstream was approved in principle in 2020-2021 and formally constituted by the GMTA Regulatory Committee in September 2021. The Coalition continued efforts to support GMTA in the:

- Development of COVID-19 recommendations to IMDRF, WHO, G/AHWP regarding appropriate international benchmarks;
- Coordination towards an MDRC-related training to address pandemic/emergency elements; and
- Eventual inclusion of links to the MDRC project website and any related resources on the GMTA website.

As part of these efforts, AdvaMed staffs the GMTA Regulatory Working Group, driving MDRC objectives alongside partners from the Coalition, AdvaMed, MedTech Europe, Mecomed, private companies, and standard developing organizations.

Activity #12.2 – The Coalition will promote, ensure, measure, and report the engagement of women throughout the implementation of the project in all geographies.

In all project activities, including trainings, MDRC tracks the participants and their gender identification, when reported. A breakdown of the engagement of women under this activity will be detailed further

down in this report.

Africa

Activity #12.6 – Tier One and Two Regional Meetings/Trainings (Timing is subject to the issuance of concurrence by the USAID Mission to Kenya. Preliminary dates are included below and are subject to change.)

Regional

During Q2, MDRC laid the groundwork for a series of regional and continental trainings on GRP and implementation. MDRC also submitted a new budget proposal to reallocate resources to the Africa Liaison. The primary functions of the Africa Liaison include:

- Role 1 (Kenya National Focus): Provide dedicated support to MDRC partners in Kenya, principally with Kenya Pharmacy and Poisons Board (PPB), focused on national MEL plan implementation.
- Role 2 (South Africa and Ghana Focus): Provide dedicated support to MDRC partners in South Africa and Ghana, principally with the South Africa Health Products Regulatory Authority (SAHPRA) and the Ghana Food and Drugs Authority (GFDA), focused on national-level MEL plan implementation in those countries.
- Role 3 (AMDF Focus): Provide support to PPB and SAHPRA in their roles leading AMDF and provide support to the AMDF Secretariat focused on continental MEL plan implementation.

A candidate for the role of Africa Liaison was identified in Q1 2023. MDRC is in the process of working with ANSI to contract the Liaison and set a start date of the beginning of July 2023. The Africa Liaison will be joined on the ground by several members of the Regulatory Coalition Secretariat to ensure successful coordination and implementation of training engagements.

From April through June 2023, MDRC held numerous meetings with FDA regarding the capacity building training curriculum for regional and continental trainings in 2023. Due to FDA travel requirements and NRA schedules, MDRC shifted planned trainings from Q2 to Q3 and Q4 2023. Marking a significant MDRC milestone, on 20 June the FDA signed off on the curriculum, which now constitutes the first ever FDA-industry developed "menu" of MD NRA training options from which to develop training sessions aligned with international reference documents and with an emphasis on GRP and use of standards. With inputs from SAHPRA, PPB, Mecomed, FDA, and MDRC, the training curriculum is the first Medtech-NRA global level curriculum jointly approved by industry and government. The curriculum marks a significant MDRC output and will be a GMTA and IMDRF contribution. It is the hope of MDRC that this curriculum will be repurposed and used by other projects seeking to advance global regulatory harmonization and foundational GRP.

Ghana

In Q2, Ghana FDA (GFDA) signed the MOU and MDRC met with members of the Ghana Mission to share an overview of the work to date and MDRC's plans for the remainder of the year. MDRC shared that Ghana was selected as a project country given its strategic regional importance – medical technology is rarely produced in just one country and so harmonization of standards across countries ensures the existence of functional and resilient supply chains. Ghana officials will be able to attend virtual trainings in August, and MDRC can consider priority areas flagged by Ghana.

Kenya

In April, USTR convened a meeting with the Kenya Delegation, during which MDRC provided an update on SA2 and noted the strong cooperation between the MDRC team, U.S. governments bodies including FDA, and relevant Kenyan government bodies including PPB and Kenya Bureau of Standards (KEBS). PPB reiterated the strong collaboration with the MDRC and the positive expectations of the project.
PPB input was critical to the development of the training curriculum, and MDRC held frequent discussions with PPB and KEBS to finalize the training schedule to meet regulators' needs and make the best use of available funds from U.S. government.

South Africa

During Q2, MDRC continued its communications and coordination with SAHPRA with a view to scheduling MDRC South Africa trainings in alignment with the schedule of FDA, PPB and AMDF trainings.

Indo-Pacific

Activity #12.10 – Tier Two Regional Meetings/Trainings

During Q2 2023, the team engaged in a series of meetings and activities in Indonesia to promote GRP in medical technology regulation. They requested a meeting with the Director General Rizka to discuss checklists on GRP and Conformity Assessments. MDRC also held a meeting with Professor Laksono and the MoH team to discuss the socialization of checklists, capacity building needs, and the review of MoH's current SOP on medical device regulation. MDRC prepared a report summarizing activities conducted in Indonesia between 2022 and 2023, including key achievements, workshop outcomes, and participant numbers. The report was submitted for review to the USAID post in Jakarta and will be shared with the MoH team once the review is completed.

Furthermore, the team reviewed the MoH's current SOP for the medical device regulatory approval process as well as a gap analysis on capacity building requirements, and will respond with recommendations to the MoH for plugging the gaps and implementing international best practices.

Latin America

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

Throughout Q2, MDRC leveraged several global platforms to advance its workstream objectives: connecting foundational GRP to regulatory frameworks. On 7 June and via several follow up meetings, MDRC through AdvaMed held several engagements with the FDA and MDRC Steering group medtech companies regarding planning for the remaining 2023 meetings of the IMDRF and GHWP with a focus on *Regulatory Reliance*, a core aspect of which is use of international standards and foundational GRP. The MDRC team also coordinated with the Pan American Health Organization (PAHO) regarding IACRC engagement with the PAHO RED-PARF meeting of regional medtech regulatory authorities planned for 12-13 October in El Salvador. The IACRC is planning MDRC engagements in conjunction with this regional meeting for 9-11 October. These meetings provided a timely opportunity for MDRC to further its collaborations and advance MEL plan metrics with the MDRC national, regional and global partners with

a focus on the establishment of international medtech reference documents essential for regulatory convergence and COVID-19 response and recovery efforts.

During Q2, MDRC also continued to engage in regular coordination meetings with USAID and SA2 projects; the Medicines, Technologies, and Pharmaceutical Services (MTaPS) and Quality of Medicines Plus (PQM+). These coordinating meetings presented an opportunity for project teams to share learnings, identify priority areas and resource constraints, and discuss updates on convenings of key organizations. Going forward, USAID and SA2 projects will use the monthly meetings as work meetings to increase coordination efforts and develop a common set of knowledge tools and reference guides that any USAID project could use.
Moreover, under this reporting the team met with the United States Trade Representative (USTR) to discuss GRPs in the region. MDRC provided an update on the implementation of GRPs in Mexico as well as Colombia, where the Ministry of Health has published the Processes and Procedures document. This document will serve as a basis for the National Planning Department (DNP) to develop an overview guide of GRP. The implementation of GRP at Tiers One and Two in Colombia was recognized with an award by the Government of Colombia for the approval and publication of GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. MDRC relayed its productive March meetings with DNP, Public Function, and the Ministry of Commerce, Industry, and Tourism (MinCit). Regarding Mexico, USTR confirmed the absence of a representative at the WTO/TBT Committee, which posed challenges in advancing bilateral topics.

MDRC also conducted meetings with industry groups, and private companies such as Johnson & Johnson, to discuss collaboration opportunities in the region. There is strong commitment among industry to address regulatory bottlenecks through the work of the MDRC.

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

Brazil

In April, the team held meetings with the Ministry of Industry and Development – Division of Competitiveness and Regulatory Practices (MDIC/SCPR) Secretary, Andrea Macera. The importance of effective storytelling for GRPs was discussed, and Secretary Macera proposed partnering with the Inter-American Development Bank (IDB) to develop a national strategy for GRP. MDIC colleagues also suggested using the checklist as a pilot among regulators to verify compliance with GRP and TBT rules. They proposed using it with the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO) as part of an online platform.

MDRC also continued conversations with the Brazilian Technical Committee for Clinical Analysis and In Vitro Diagnostics (ABNT CB-36) administered by the Brazilian Society for Clinical Analyses (SBAC), and the Brazilian Chamber for In Vitro Diagnostics (CBDL) to discuss the internalization of ISO 18113 series of standards.

During Q2, MDRC's meetings in Brasilia with MDIC also included discussions on the implementation of the U.S.-Brazil Agreement on Trade and Economic Cooperation (ATEC) – Annex II (GRP) provisions and on its potential expansion with provisions for medical devices. MDRC met with the Secretariat of Foreign Trade (SECEX) to present on the work underway and possible development of a specific sectoral annex

on medical devices. MDRC also met with ANVISA and CAMEX to discuss the possibility of expanding the agreement, and how it might bolster regulatory harmonization.

Additional stakeholder engagement included meetings with the Secretariat of Competitiveness and Regulatory Practices (SCPR) and industry on the submitted public consultation for cost reduction.

Lastly, MDRC presented GRP strategies at Hospitalar 2023, an annual health trade sector fair in Latin America. The presentation included Brazilian Association of Importers of Medical and Hospital Equipment, Products and Supplies (ABIMED) and informed the ABIMED membership and broader Brazilian health sector stakeholders on the importance of GRP to health, medtech and trade outcomes, and the importance of private-sector co-responsibilities in the development of technical regulations and standards.

Colombia

In Q2 2023, MDRC continued to lead the formal implementation and institutionalization of GRP in Colombia and had several engagements with the Ministry of Health (MoH). While the work of the Colombia Liaison concluded in April, MDRC remains available to support training sessions on GRP. To ensure the continuation of work, MDRC prepared a general report on the global advances achieved during the methodological accompaniment by the MDRC Colombian Liaison, along with a detailed report for each project that explains all the stages applied in harmony with the procedure approved by the legal office of the Ministry of Health.
MDRC held three training sessions in April targeting regulatory authority and citizen participation:

- 14 April: MoH's legal office team delivered a presentation, and a total of 81 participants, including technical staff and lawyers responsible for implementing GRP, attended the training.
- 21 April: MDRC, along with the Administrative Department of the Civil Service (DAFP) and the Superintendency of Industry and Commerce, delivered presentations. MDRC covered citizen participation in the regulatory agenda, while DAFP discussed the identification of regulated procedures. The Superintendency provided guidance on evaluating the impact of new regulations on competition. In total, 58 participants, including technical staff, lawyers, and representatives from mission areas responsible for implementing GRPs, attended the session.
- 28 April: The session focused on Processes and Procedures and included a presentation on legal techniques for writing regulatory texts and requirements for regulations involving public resources. A total of 42 participants, including technical staff and lawyers responsible for implementing GRPs, were present.

Following the trainings, MDRC met with private sector representatives from government affairs, regulatory affairs, and regional and local teams to discuss how government personnel changes could impact the advancement of the MDRC project.

During Q2, MoH continued to pose questions regarding the OTC agreement applied to resolution 2968 of 2015, which is related to sanitary requirements that must be met by establishments that manufacture and adapt medical devices on external orthopedic technology measurement. MDRC prepared and sent the final concept intended to affirm whether or not is a technical regulation.

Finally, MDRC met with INVIMA to define next steps that will allow progress in the second semester of the year. It was agreed to send the results obtained with the participation of INVIMA and share the procedure adopted by the Ministry of Health regarding the adoption of GRP in the technical regulation.

Mexico

In Q2 2023, MDRC continued efforts to develop and approve checklists for implementing GRP in key governmental bodies. These checklists will help build national quality infrastructure and facilitate compliance with international trade obligations. In turn, this will promote patient access to vital medtech and generate resilience for future health crises. MDRC continued to advance several workstreams, including addressing trade concerns presented by NOM-241. A summary of MDRC meetings and engagements for Q2 is provided below.

From April to June 2023, MDRC held multiple meetings with the Mexican Federal Commission for the Protection of Sanitary Risk (COFEPRIS) to review ongoing MDRC workstreams including stability studies and emergency updates on NOM-241. COFEPRIS shared that it is drafting a document on regulatory certainty for medical devices. Although the "Strategy for Regulatory Certainty" is not yet complete, COFEPRIS' International Affairs Department has completed a draft and is awaiting feedback from its legal department. The group also discussed the U.S.-Mexico High-Level Economic Dialogue (HLED) report status, and it was shared that COFEPRIS is still revising the report to respond to U.S. requests.

With regard to NOM-241, MDRC continued to hold conversations with COFEPRIS regarding regulatory policies that will result in deviations from international standards. COFEPRIS also committed to putting NOM-241 in for revision as a part of the 2024 regulatory agenda to address the other content and process issues.

MDRC also held engagements with AMID, INDEX, and CANIFARMA member companies on NOM-241.

On 28 April, COFEPRIS, through the Commission of Sanitary Promotion, published Oficio No. COFEPRIS-CFS-214-2023 which excludes the manufacturers under the IMMEX program from the scope of NOM-241.

On 14 June, as a response to a request from the Ministry of Economy, MDRC provided an analysis of legal alternatives to produce interpretation criteria to the new version of NOM-241.

Peru

Under this reporting quarter the team conducted an interactive training session with the Peruvian MD Joint Committee, covering GRP concepts and country-specific items. The involvement of technical committees at the National Institute of Quality (INACAL) was also discussed, with Medtronic taking a leading role in analyzing opportunities to include standards in the agenda. On the same day, MDRC met with ALAFARPE to present an overview of MDRC and explore collaboration opportunities. Future coordination would be managed through the MD Joint Committee of ALAFARPE-AmCham.

On 23 June, a proposal for the capacity building plan for the remainder of 2023 was discussed with the ALAFARPE-AMCHAM MD Joint Committee. The final document will be submitted to DIGEMID for their evaluation and definition of next steps.

2.4. Implementation Challenges

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

CWSC has uncovered limited information from their own contacts with respect to research questions #3 and #4 regarding additional barriers to NQI beyond those presented in environment and water-related laws and workforce development. Therefore, CWSC is exploring those topics with IAPMO and IAPMO's contacts in the plumbing industry.

Originally, CWSC planned to hold two separate education and engagement sessions: one for government, and one for private stakeholders. However, they are determining whether or not one session will be held for both so as to better engage all national level stakeholders.

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

Delays in obtaining the required J-1 Visas necessary for the West African participants proved problematic for the U.S. Study Tour. Although all focal points eventually obtained their visa, this long procedure created more uncertainty in the planning stages for the Study Tour to take place.

Activity #8 – Utility Management Standards Training for water sector utilities

Hard copies of all 15 ANSI/AWWA Utility Management Standards were shipped to Zambia for the 22 in-person attendees in Africa. Unfortunately, the shipment to Zambia was detained and eventually irrecoverable. The Africa workshop attendees have been provided access to download the 15 standards from the awwa.org website to replace the hard copy standards.

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

Government Mobilization

Ghana

As a result of MDRC's partnership with local stakeholders (i.e. U.S. Embassy Officials in Accra) to conduct outreach with Ghana's Tier One and Two agencies, MDRC contacted Ghana's Ministry of Trade and Industry (MOTI) and Food and Drug Administration (Ghana FDA). MDRC was able to renew conversations with the Government of Ghana and draft two MOUs to guide workstream implementation at Tiers One and Two. Those MOUs were submitted for MOTI and Ghana FDA's approval in Q3 2022.

In Q4 2022, MDRC experienced continued delays in engagement with those governmental stakeholders. One major challenge is the technical capacity of those government officials. For example, officials' do not always accept correspondence from external emails, which makes scheduling difficult. In response, MDRC conducted additional outreach via WhatsApp and through U.S. Embassy Officials. Despite that outreach, MDRC still experienced difficulty scheduling engagements in Ghana.

Although Ghana FDA signed the MOU in Q2 2023, there is a limited timeline for engagement to fully develop the workstreams in the country. MDRC would welcome the participation of Ghana regulatory authorities during hybrid trainings scheduled to be held in Kenya in August as well as continental trainings

in November, but the opportunity for in-person engagements in Ghana is limited.

Mexico

In Q1 2023, MDRC experienced difficulties in making progress with its workstreams with COFEPRIS. MDRC sought to increase frequency of its meeting with COFEPRIS during Q2 2023, and discussions were focused on NOM-241 to address concerns about bottlenecks and technical barriers to trade. In April, COFEPRIS, through the Commission of Sanitary Promotion published Oficio No. COFEPRIS-CFS-214-2023 which excludes the manufacturers under the IMMEX program from the scope of NOM-241. In May, MDRC along with AMID, 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. In June MDRC provided an analysis of legal alternatives to produce interpretation criteria to the new version of NOM-241.

WHO MedTech Guidance

As noted in the Q2 2022 report, 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 believes that a number of systemic WHO practices work at cross-purposes with both MDRC's efforts to build NRA capacity as well as guidance developed by the IMDRF, FDA/CDRH, WTO and the WHO.

In Q2 2023, project partners, such as the FDA/CDRH, agree with and regularly express these concerns directly to the WHO.

As MDRC continues its work, those practices may hinder MDRC's ability to fully realize its project objectives.

Coordination on Aid for MD NRA Capacity Building

From the project's inception, MDRC has worked to coordinate with USAID, FDA/CDRH and other USAID project teams to ensure an aligned and non-duplicative approach to capacity building. Through the establishment of a coordination team, all parties have worked to share information and ensure proper differentiation between medtech and medicines in their project workstreams. MDRC believes that improving the information sharing mechanisms between all parties will be critical to future successful capacity building.

In Africa, for example, MDRC has coordinated with USAID and USTDA to structure MDRC programming to be supportive of and complementary.

3. STAKEHOLDER PARTICIPATION AND INVOLVEMENT

Activity #	Sub activity #	Country	Meeting/ Event	Date	Participants
5	5.7	West Africa	US Study Tour on Petroleum Harmonization	June 24-29, 2023	Total: 8 (4 private sector, and 3 Women)
8	8.3	Zambia	AWWA Training for water sector utilities	April 24-25, 2023	22 attendees 8 female, 14 male Government sector
12	12.6	Latin America	Webinar on Stability of Medical Devices	1 June	334 attendees 234 female, 96 male, 4 did not declare gender (65 private sector)
12	12.6	Colombia	MoH training on the implementation of GRP	14 April	81 attendees 57 female, 24 male (0 private sector)
12	12.6	Colombia	Department of the Civil Service (DAFP) and the Superintendency of Industry and Commerce Workshop on citizen participation and the regulatory agenda	21 April	58 attendees 42 female, 16 male (0 private sector)
12	12.6	Colombia	Training on Processes and Procedures	28 April	51 attendees 32 female, 19 male (0 private sector)

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 **6** trainings to report. A breakdown of the different workshops is presented below by activity.[1]

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

The target for this activity was to hold **1** training event during this reporting quarter. With the organization of the US Study Tour in Denver in June 2023, and this target was indeed reached.

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

Activity #8 – Utility Management Standards Training for water sector utilities

In Q2 2023, AWWA set a target of **1** for Africa and **0** for India. The final workshop for this activity in Africa took place in person in Zambia in April 2023. The demand to have the final training in person this quarter demonstrated a very strong buy in from local stakeholders and the ability for the activity to have a greater impact in the region, developing stronger relationships with key stakeholders.

As the training in Zambia marked the last event for this activity there are no targets to be set for the next quarter.

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

For Q2 2023, MDRC set a target of **1** workshop under this indicator and it was able to exceed this target by hosting three additional training in Colombia on GRPs demonstrating the lasting impact of a local consultant on the ground pushing for SA2 objectives of harmonization and better conformity assessment to facilitate cross border trade.

For Q3 2023, MDRC sets a target of **1** workshop under this indicator.

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 **3** workshops to report cumulating to a total of **554** participants. A breakdown of the different participants in said workshops is presented below by activity.[2]

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

The target under this indicator was set at **8** for this quarter. Given that the team was able to host the Study Tour in Denver it was able to reach this target demonstrating the strong involvement from both

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

[2] *Idem*

public and private sector in the region to facilitate cross border trade.

As mentioned the Study Tour marked the conclusion of the activities under this program so there are no more targets to set.

Activity #8 – Utility Management Standards Training for water sector utilities

In Q2 2023, AWWA set a target of **30** for Africa and **0** for India. The target for Africa was lower than expected as just 22 participants joined the in-person 2-day workshop. Logistical challenges and approval for travel within invited water utilities caused this discrepancy. However, a total of 59 participants engaged across the webinar and in-person training series, demonstrated strong interest for AWWA standards trainings by utilities.

This was the last activity under this program so there are no targets to set for the next quarter.

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

For Q2 2023, the team had a target of **75** participants; which it exceeded by developing more training in Colombia. All trainings combined had a total of **524** participants

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 Q3 2023, MDRC sets a target of **75** participants under this indicator.

5. LESSONS LEARNED

Activity #5 – Economic Community of West African States (ECOWAS) Harmonization of Petroleum Standards

The focal points benefited from engaging with ASTM members both in the context of the standards development meetings, as well as on the margins of the meetings in a separate classroom setting. It was an added benefit to involve other attendees from the region who were present at the meetings in Denver.

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 Q1 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. For in-person attendees, MDRC continues to learn how to effectively navigate USAID J-1 visa requirements which are more problematic to secure than the B1-B2 visas required for the same authorities and private sector attendees participating in USTDA trainings. 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 attendees. These learnings are increasingly critical in the effective execution of capacity building.

6. PLANNED ACTIVITIES FOR NEXT QUARTER, INCLUDING UPCOMING EVENTS

Activity #	Sub activity #	Country	Publications/ Reports	Meeting/ Event	Date	Location	USAID participation
12	12.6	Africa		Regional training sessions with medical device NRAs utilizing a curriculum developed by FDA and GMTA.	August 14-18	Hybrid	Yes