GLOBAL ENVIRONMENT FACILITY
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Phasing out mercury measuring devices in healthcare

Part I: Project Information

GEF ID
10716

Project Type
FSP

Type of Trust Fund
GET

CBIT/NGI
- [ ] CBIT
- [ ] NGI

Project Title
Phasing out mercury measuring devices in healthcare

Countries
Global, Burkina Faso, India, Montenegro, Uganda, Albania

Agency(ies)
UNEP

Other Executing Partner(s)
World Health Organization (WHO)

Executing Partner Type
Others

GEF Focal Area

Chemicals and Waste

Taxonomy

Focal Areas, Chemicals and Waste, Waste Management, Hazardous Waste Management, Mercury, Influencing models, Convene multi-stakeholder alliances, Strengthen institutional capacity and decision-making, Transform policy and regulatory environments, Stakeholders, Beneficiaries, Communications, Awareness Raising, Public Campaigns, Behavior change, Education, Type of Engagement, Participation, Partnership, Information Dissemination, Consultation, Private Sector, SMEs, Civil Society, Non-Governmental Organization, Gender Equality, Gender Mainstreaming, Sex-disaggregated indicators, Capacity, Knowledge and Research, Knowledge Generation, Learning, Theory of change, Adaptive management, Indicators to measure change, Capacity Development, Targeted Research, Sound Management of chemicals and waste, Disposal, Best Available Technology / Best Environmental Practices

Rio Markers

Climate Change Mitigation

Climate Change Mitigation 0

Climate Change Adaptation

Climate Change Adaptation 0

Duration

60 In Months

Agency Fee($)

758,100.00

Submission Date

9/28/2020

A. Indicative Focal/Non-Focal Area Elements

Programming Directions	Trust Fund	GEF Amount($)	Co-Fin Amount($)
CW-1-1	GET	7,980,000.00	56,280,000.00
	Total Project Cost ($)	**7,980,000.00**	**56,280,000.00**

B. Indicative Project description summary

Project Objective

To eliminate uncontrolled releases of mercury from healthcare settings

Project Component	Financing Type	Project Outcomes	Project Outputs	Trust Fund	GEF Amount($)	Co-Fin Amount($)
Component 1: Development and implementation of national health-system wide strategies for phasing out the import, export and manufacture of mercury thermometers and sphygmomanometers in line with WHO recommendations and related provisions of the Minamata Convention.	Technical Assistance	Outcome 1: All countries participating in the project have developed national health-system wide strategies for phasing out the import, export and manufacture of mercury thermometers and sphygmomanometers in line with WHO recommendations and related provisions of the Minamata Convention.	Output 1.1: National strategies for phasing out mercury-added thermometers and sphygmomanometers in healthcare developed in selected countries.	GET	1,500,000.00	1,000,000.00

Component 2: Implementation of national strategies to phase out manufacture, import and export in all project countries, and demonstrations of a phase out in use in at least 3 countries.	Technical Assistance	Outcome 2: An environment conducive to the cessation of procurement and manufacture of mercury-added medical measuring devices is facilitated in selected countries.	Output 2.1: Phasing-out mercury-added thermometers and sphygmomanometers used in healthcare, from procurement to the safe and environmentally sound interim-storage of mercury-containing wastes. Output 2.2: Mercury-containing medical waste is managed in an environmentally sound manner, from storage to disposal. Output 2.3: Awareness raising towards Indian manufacturers	GET	3,750,000.00	40,500,000.00

Component 3: Knowledge management	Technical Assistance	Outcome 3: Improved and disseminated knowledge on the phasing-out of mercury-added medical measuring devices, including on their manufacture, import and export.	Output 3.1: WHO technical and information materials developed and/or updated. Output 3.2: UNEP technical guidance developed on the management of mercury-containing healthcare waste. Output 3.3: Good practice examples and lessons learned from the implementation of project components 1 & 2 documented and disseminated, including through WHO channels and the UNEP Global Mercury Partnership.	GET	2,250,000.00	12,000,000.00
Component 4: Project results are available nationally and shared with other countries participating in this project, and globally.	Technical Assistance	Project results are available nationally and shared with other countries participating in this project, and globally	Output 4.1: Monitoring and evaluation activities carried out as per the GEF requirements.	GET	100,000.00	100,000.00
				Sub Total ($)	**7,600,000.00**	**53,600,000.00**

Project Management Cost (PMC)

GET	380,000.00	2,680,000.00
Sub Total($)	**380,000.00**	**2,680,000.00**
Total Project Cost($)	**7,980,000.00**	**56,280,000.00**

C. Indicative sources of Co-financing for the Project by name and by type

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Investment Mobilized	Amount($)
GEF Agency	UNEP	In-kind	Recurrent expenditures	100,000.00
Others	WHO	In-kind	Recurrent expenditures	7,087,600.00
Others	UNEP Global Mercury Partnership	In-kind	Recurrent expenditures	800,000.00
Recipient Country Government	India	In-kind	Recurrent expenditures	1,000,000.00
Recipient Country Government	India	Public Investment	Investment mobilized	35,000,000.00
Recipient Country Government	Albania	Public Investment	Investment mobilized	3,000,000.00
Recipient Country Government	Burkina Faso	Public Investment	Investment mobilized	3,292,400.00
Recipient Country Government	Montenegro	Public Investment	Investment mobilized	3,000,000.00
Recipient Country Government	Uganda	Public Investment	Investment mobilized	3,000,000.00
			Total Project Cost($)	**56,280,000.00**

Describe how any "Investment Mobilized" was identified

In the case of Indian manufacturers, investment mobilised represents the net capital and human resource costs of transitioning production lines to Hg free. In the case of ministries of environment, investment mobilised captures additional capital and human resource costs associated with improved handling of Hg-contaminated wastes. In the case of ministries of health, investment mobilised captures procurement of Hg-free equipment that would not have occurred in the absence of the project and associated human resource costs. To calculate the cost of Hg-free equipment procured, a 100 % phase out of Hg-added equipment was assumed in the three projects targeted as part of Component 2 and a 25 % phase out was estimated for the remaining two non targeted countries. Low, mid-point, and high cost estimates were calculated based on available data and the mid-point was used for co-financing estimates. These calculations are consistent with those used to determine GEBs, described below.

D. Indicative Trust Fund Resources Requested by Agency(ies), Country(ies), Focal Area and the Programming of Funds

Agency	Trust Fund	Country	Focal Area	Programming of Funds	Amount($)	Fee($)	Total($)
UNEP	GET	Global	Chemicals and Waste	Mercury	7,980,000	758,100	8,738,100.00
				Total GEF Resources($)	**7,980,000.00**	**758,100.00**	**8,738,100.00**

E. Project Preparation Grant (PPG)

PPG Required ☑

PPG Amount ($)

200,000

PPG Agency Fee ($)

19,000

Agency	Trust Fund	Country	Focal Area	Programming of Funds	Amount($)	Fee($)	Total($)
UNEP	GET	Global	Chemicals and Waste	Mercury	200,000	19,000	**219,000.00**
				Total Project Costs($)	**200,000.00**	**19,000.00**	**219,000.00**

Core Indicators

Indicator 9 Reduction, disposal/destruction, phase out, elimination and avoidance of chemicals of global concern and their waste in the environment and in processes, materials and products (metric tons of toxic chemicals reduced)

Metric Tons (Expected at PIF)	Metric Tons (Expected at CEO Endorsement)	Metric Tons (Achieved at MTR)	Metric Tons (Achieved at TE)
23.96	0.00	0.00	0.00

Indicator 9.1 Solid and liquid Persistent Organic Pollutants (POPs) removed or disposed (POPs type)

POPs type	Metric Tons (Expected at PIF)	Metric Tons (Expected at CEO Endorsement)	Metric Tons (Achieved at MTR)	Metric Tons (Achieved at TE)

Indicator 9.2 Quantity of mercury reduced (metric tons)

Metric Tons (Expected at PIF)	Metric Tons (Expected at CEO Endorsement)	Metric Tons (Achieved at MTR)	Metric Tons (Achieved at TE)
23.96			

Indicator 9.3 Hydrochloroflurocarbons (HCFC) Reduced/Phased out (metric tons)

Metric Tons (Expected at PIF)	Metric Tons (Expected at CEO Endorsement)	Metric Tons (Achieved at MTR)	Metric Tons (Achieved at TE)

Indicator 9.4 Number of countries with legislation and policy implemented to control chemicals and waste (Use this sub-indicator in addition to one of the sub-indicators 9.1, 9.2 and 9.3 if applicable)

Number (Expected at PIF)	Number (Expected at CEO Endorsement)	Number (Achieved at MTR)	Number (Achieved at TE)

Indicator 9.5 Number of low-chemical/non-chemical systems implemented, particularly in food production, manufacturing and cities (Use this sub-indicator in addition to one of the sub-indicators 9.1, 9.2 and 9.3 if applicable)

Number (Expected at PIF)	Number (Expected at CEO Endorsement)	Number (Achieved at MTR)	Number (Achieved at TE)

Indicator 9.6 Quantity of POPs/Mercury containing materials and products directly avoided

Metric Tons (Expected at PIF)	Metric Tons (Expected at CEO Endorsement)	Metric Tons (Achieved at MTR)	Metric Tons (Achieved at TE)
98.36			

Indicator 11 Number of direct beneficiaries disaggregated by gender as co-benefit of GEF investment

	Number (Expected at PIF)	Number (Expected at CEO Endorsement)	Number (Achieved at MTR)	Number (Achieved at TE)
Female	2,400,000			
Male	1,200,000			
Total	3600000	0	0	0

Provide additional explanation on targets, other methodologies used, and other focal area specifics (i.e., Aichi targets in BD) including justification where core indicator targets are not provided

The project will phase out mercury-added medical measuring devices at a rate of 20 % per year from the baseline resulting in a complete phase-out of these devices within the project's timeframe. This phased approach will result in a total of 23,956 kg mercury avoided (sub-indicator 9.2). This estimate is based on certain assumptions, explained below. With the exception of India, which has an exemption until 2025, each of the countries in the project is obligated to have phased out mercury importation by 2020, before the project start date. Thus GEBs are calculated based on procurement from domestic stocks only. Because limited data are available on the quantity of these stocks they are approximated based on known import values from previous years. The estimates presented herein will be improved during the PPG phase. We calculate that the target countries procure thermometers and sphygmomanometers containing approximately 3,418 kg Hg and 1,941 kg Hg, respectively, on an annual basis. This work will take place in three countries as part of Component 2. For the purpose of determining the project's global environmental benefits, we utilize the values for current annual procurement in Albania, India, and Uganda. These countries procure an estimated total amount of 3,537 kg Hg in mercury-added medical devices per year. Assuming an annual replacement amount of 707 kg (3,537 kg/ 5 years), and an annual phase-out of 20 %, the project will phase out 707 kg in year one, 1,415 kg in year 2, 2,122 kg in year 3 and so on. The net result of these activities will be a total of 10,610 kg of mercury procurement avoided. We further estimate that through dissemination activities, procurement in the remaining 2 project countries will reduce at a rate of 5 % per year for a net avoidance of 1,367 kg. Thus the total amount of Hg procurement avoided will be 11,978 kg. Figure 1 provides a summary for the three countries targeted as part of Component 2. The project will also endeavour to improve how mercury waste is handled. Assuming the same 20 % annual uptake of improved waste management practices, the project will result in a proportionate 11,978 kg of mercury managed soundly. Thus the project's total contribution to indicator 9.2 is calculated as 23,956 Hg. Sub-indicator 9.6 estimates include the total mass of equipment containing mercury. To calculate this value, we estimate the weight of a single thermometer as 15 grams and the weight of a single sphygmomanometer as 500 grams. Applying the same assumptions as above, this results in a total 98,358 kg Hg-contaminated material avoided. These estimates are preliminary and based on the best available data. They will be improved through stakeholder engagement and data collection done as part of the Project Preparation Grant (PPG) phase. The project will also result in the improved management halogen containing wastes and will therefore result in reductions of dioxin creation. Baseline data were not available at the time of drafting the PIF and will be identified during the PPG (for core indicator 10). The total project beneficiaries (indicator 11) was calculated as the total number of physicians, midwifes and nurses in the 5 target countries. Data were not available for health care waste management personnel, though these individuals will directly benefit from the project. The patient population and further the population of the target counties will benefit as well. Thus the use of the physician, midwife and nurse population, is highly conservative. Gender composition and total workforce data were taken from the WHO Global Health Observatory.

Part II. Project Justification

1a. Project Description

a) The global environmental and/or adaptation problems, root causes and barriers that need to be addressed

Mercury is a naturally occurring silvery grey metal that is liquid at room temperature. It has a high expansion coefficient and amalgamates with several other metals, including gold and silver. These characteristics have led to several important applications, such as its use in thermometers, blood pressure measuring devices (sphygmomanometers), electric switches and as an amalgamate in gold and silver mining operations.

Mercury is highly toxic to humans and ecosystems and is considered by WHO as one of the top ten chemicals or groups of chemicals of major public health concern. Exposure to mercury can result in adverse impacts on the nervous, digestive and immune systems, lungs and kidneys. Children are especially vulnerable and may be exposed directly by eating contaminated fish. Methylmercury bioaccumulated in fish and consumed by pregnant women may lead to neurodevelopmental problems in the developing foetus. Transplacental exposure is the most dangerous, as the foetal brain is very sensitive. Neurological symptoms include intellectual disability, seizures, vision and hearing loss, delayed development, language disorders and memory loss.

Mercury occurs in various forms and compounds, with human exposure somewhat mediated by the bioavailability of each. Elemental mercury (Hg^0) is the form most commonly used in industrial applications and released from natural sources. Exposure to elemental mercury occurs primarily through inhalation, with relatively little absorption through either the skin or gastrointestinal tract. When released in the environment elemental mercury can be converted to the more bioavailable methylmercury (CH_3Hg) through interactions with various microorganisms. Methylmercury is lipophilic and bioaccumulative, meaning that organisms tend to absorb it more quickly than they expel it. These characteristics in turn contribute to its tendency to biomagnify, meaning that creatures further up the food chain contain proportionally more mercury; shark or albacore have proportionally more mercury than salmon, for instance. Accordingly, humans consuming fish vast distances from mercury sources can incur mercury-attributable disease.

Releases in healthcare settings are primarily associated with damaged equipment and poor waste management practices. Mercury-added thermometers are comprised of a vacuum sealed glass tube enclosing a small bead of mercury (0.61–2.25 grams Hg, depending on type) which expands or contracts in response to temperature.[1] They have a lifespan of 5–10 years and are typically only discarded when the glass chamber is ruptured and a spill occurs.[2] Mercury evaporates at room temperature; an adequate quantity in a confined space can result in acutely poisonous air levels.[3] Individual thermometers are unlikely to present such a risk. A 2006 investigation in Chicago (USA) homes found that mercury air concentrations following thermometer spills did not exceed the applicable USEPA threshold of 1 $\mu g/m^3$.[4]

[5]

Mercury-added sphygmomanometers contain substantially more mercury than thermometers (64–200 grams), though are much less prone to rupture.[5] In rare cases poisoning has been documented at spill sites in residential settings.[6] The devices themselves are comprised of a U-shaped glass tube containing a column of mercury. The column rises or falls in response to air pressure introduced by the blood pressure cuff. Because this air-mercury interface is imperfect, a majority of sphygmomanometers experience some level of mercury release over their lifetime, though in concentrations highly unlikely to produce adverse health outcomes.[7]

While any one piece of mercury-added medical equipment is unlikely to pose a significant human health risk and the environment, the aggregate impact of these devices is considerable. A 2004 study in Canada found more than 2 tons of annual mercury releases from thermometers alone.[8] Likewise a 2011 NGO study in India estimated annual national releases of 8 tons, with 69 % coming from poorly disposed sphygmomanometers and the balance coming from thermometers.[9] Globally, more than 10 % of annual mercury releases are attributable to the intentional use of mercury in products (a category which includes medical measuring devices as well as light bulbs and other products).[10] A 2017 UNEP report calculated the global use of mercury in 'measuring a control devices,' a category comprised nearly entirely of thermometers and manometers, as 330 tons.[11]

Mercury-added measuring devices have formed an essential component of medicine for centuries. The first mercury-added thermometer was developed in Germany in the early 18th century (by Fahrenheit); sphygmomanometers came about 170 years later in Austria. Owing largely to environmental and human health concerns, high-income countries began to phase-out the manufacture and use of these devices beginning in the early 2000s.

The instruments are also imperfect. Mercury-added sphygmomanometers are prone to produce inconsistent results either from user error or equipment issues.[12] One study of a hospital in London found that 38 % of the units were obscured by dirt or mercury oxidation, and current validation certificates were only available for 5 %.[13] Relatedly, 'terminal digit preference,' whereby a medical worker rounds the last digit up or down when recording systolic or diastolic blood pressure, could have significant public health implications.[14] A 1993 study of the medical charts of 28,841 pregnant women in Quebec found that > 78 % of blood pressure readings ended in '0,' while only 2 % ended in an odd number other than '5.'[15] Digital instruments sidestep this issue somewhat by presenting a discrete and immediately discernible value, while dial-based (i.e. aneroid) devices are less subject to obscured values from oxidation. Accordingly, there has been a general shift towards digital measuring devices resulting in substantial reductions in the use of mercury, the facilitation of more precise measurements and a broader diffusion of medical monitoring.

The Minamata Convention on Mercury entered into force on 16 August 2017. The Convention, which was shepherded into existence by the United Nations Environment Programme (UNEP), currently has 128 Signatories and 122 Parties (countries where it has been ratified). It covers a range of issues associated with mercury production, use, waste and disposal, providing a list of uses in which the manufacture, import and export are restricted, and applicable phase-out dates or reduction targets. The manufacture, import and export of sphygmomanometers and thermometers have a specified phase-out date of 2020. Parties may request exemptions. India, which is included in the project, has requested such an exemption for the manufacture of Hg-added sphygmomanometers and thermometers among other devices until 2025.

In practice the Convention targets relating to medical measuring devices have already been achieved by most high-income countries. The European Union removed mercury-added thermometers and sphygmomanometers from the market in 2014.[16] In the United States, mercury was effectively removed from medical measuring devices beginning in 2003 through a series of state laws and actions by professional associations, though no specific Federal laws exist.[17] In several low- and

middle-income countries (LMICs), too, significant progress has been made. The Philippines began phasing out mercury-containing medical measuring devices in 2008. Argentina did so in 2009; Chile in 2011.[18] Mercury is an element and cannot be created or destroyed. Thus, in accordance with the Basel Convention, mercury wastes are typically stabilized with sulphur and disposed of in specifically engineered landfills.[19]

Barriers to be addressed

Despite these successes, a number of challenges remain. Mercury-added devices have been wedded to medicine for centuries, resulting in firmly rooted perspectives and processes across the supply chain. The barriers described in this section have been identified to be addressed by the project.

Lack of knowledge on the procurement side

In both public and private hospitals many procurement officers have inadequate decision-making guidance in place.[20] There exists a general scepticism about relatively higher upfront costs of mercury-free alternatives. Procurement officers also have concerns about the acceptability of these devices by the end-user (i.e. physicians and nurses).[21] On the surface, the upfront costs of non-mercury thermometers and sphygmomanometers would appear prohibitive. The sticker price of thermometers, for example, can be upwards of 5x the cost of mercury-added devices. However even a cursory review of the life-cycle costs of both types of instruments – including procurement, maintenance, and disposal – reveals significant savings with mercury-free alternatives. A case study in Rio de Janeiro, Brazil of procurement during the year 2010–2011 found a remarkable 33 % savings in favour of digital instruments.[22] There is a need to share these lessons learned from other healthcare settings in the targeted countries.

Perspectives of the medical profession

Perhaps the most significant barrier to the adoption of mercury-free alternatives is the conviction of medical practitioners. Indeed in the United States, the first country to phase-out mercury-added medical measuring devices, the most vehement opposition came from physicians.[23] For many, the low risk of any one patient being exposed was inadequate to justify the introduction of an unproven technology. The technical merits of this argument were subsequently challenged – both by increased validation and improvements in digital equipment – and generally settled. There is now broad agreement in the US and other high-income countries on the equivalent clinical accuracy of non-mercury medical measuring devices. However, in many LMICs these important discussions have only recently begun, triggered in part by the Minamata Convention. There is a need to support accurate and informed discussion on their clinical utility. Where this has been done, physicians have quickly overcome initial apprehensions.[24]

Lack of manufacturing capacity

There is a potential risk that manufacturers of mercury-added medical measuring devices may be required to absorb any adverse financial impacts resulting from a phase-out. Some may lack the requisite skills, capacity and resources to transition product lines. More likely, however, many may have responded to the shifting market and began to add in additional non-mercury dependent product lines. A 2011 University of Massachusetts/ UNEP study evaluated the experience of two US medical device manufacturers as they transitioned to mercury free product lines, which they had done in response to shifting demand.[25] A major observation of the study was that the lack of a coherent regulatory framework in the US compelled manufacturers to maintain two separate production lines, one with mercury and one

without. These parallel lines resulted in unnecessary costs; using mercury in production required compliance and insurance expenses not associated with mercury-free devices. Accordingly, a more comprehensive and coordinated phase-out would have benefitted the producers. The study also evaluated the return on investment for transitioning to mercury-free lines, finding full cost recovery within a year.

Only one country proposed under the current project, India, has a mercury-added medical device manufacturing base. A 2020 study by the Indian NGO ToxicsLink found that these relatively smaller scale manufacturers produced equipment primarily for domestic consumption.[26] As part of that research, 17 such manufacturers were identified and their contact information shared with the project team. There is a need to support these manufacturers through the provision of technical guidance and education materials to facilitate their transition toward more sustainable product lines.

b) The baseline scenario or any associated baseline projects

<u>Alternatives to mercury-added devices</u>

Thermometers and blood pressure measuring devices have formed integral parts of medicine for 140 years. The temperature of a healthy human body is typically between 36.5–37.5 centigrade. Variations (either an increase or decrease) are an immediately discernible symptom of illness. Fever can be indicative of systemic inflammation typically in response to the presence of a pathogen (such as SARS-CoV-2). It can also indicate hyperthermia from overexertion or heat exposure. Decreases can be symptomatic of hypothermia, a potentially life-threatening condition when the body begins to shut down in response to cold.

Blood pressure is the term used to describe the force exerted by circulating blood along the walls of vascular system. Blood pressure measurements account for both systolic (the maximum pressure exerted during the beat of the heart) and diastolic (the minimum in between beats) forces). Along with temperature, pulse, breathing rate and oxygen saturation, blood pressure comprises one of the 5 ‘vital’ signs monitored by physicians. High blood pressure (i.e. hypertension) is the best indicator of heart disease, the cause of nearly 30 % of global deaths annually.[27]

Digital thermometers

Digital thermometers are a class of instruments that displays temperature in digits, first developed in the mid-20th century. The underlying mechanism can have significant variation in construction and can include: thermistors, galinston-in-glass, alcohol-dye, tympanic infrared, temporal artery infrared, thermocouple-based, phase-change, and thermochromatic liquid crystal. All digital thermometers either use body contact or infrared as a basis for measurement. When compared with mercury-added thermometers, they are equally accurate and typically much easier to use. They are also prone to significantly less user error.[28]

Blood pressure measuring devices

There are two types of blood pressure measuring devices in general use besides mercury-added sphygmomanometers: aneroid and oscillometric. All three function by compressing the brachial artery until circulation stops, and then measuring the arterial pressure once it begins again (at its maximum, i.e. systolic) and after all external pressure from the cuff has been removed (at its minimum, i.e. diastolic). Aneroid devices are fully mechanical with pressure directly exerted on the mechanism and displayed on a dial. Oscillometric devices measure differences in air pressure received against a diaphragm and display readings digitally after interpretation through an algorithm. In all cases measurements are displayed in millimetres of mercury (mmHg) owing to the long usage of sphygmomanometers. Oscillometric devices can be fully automated though are prone to error. Hybrids oscillometric/ aneroid devices also exist and are in some cases preferable.[29] Aneroid devices are comparable in cost to mercury-added sphygmomanometers, while oscillometric and hybrid units are more expensive. All require validation (ability to produce a reading in humans), calibration (adjustment to a known value) and regular maintenance.[30]

Waste management considerations

Healthcare facilities generate large and consistent streams of waste. A typical African hospital in an urban centre might produce anywhere from 0.1 to > 1 kg of waste per bed per day, while hospitals in high income countries can generate nearly 10 kg per bed per day.[31] The majority (> 85 %) of this waste will be non-hazardous, with the balance falling into one of the six following hazardous waste categories: sharps, infectious, pathological (e.g. human tissue), pharmaceutical, chemical (which includes Hg) and radioactive.[32]

Non-mercury wastes

As with other sectors in LMICs, healthcare facilities face a number of challenges associated with proper solid waste disposal, mainly due to a lack of waste-related infrastructure in the countries. Open uncontrolled dumpsites remain the most frequently employed disposal option for solid waste in LMICs. Offsite migration of contamination at these dumpsites through leaching and windblown dust is common. Deliberately set fires (to reduce volume) and spontaneous combustion (due to thermal runaway) occur as part of normal operation. When a halogen (i.e. chlorine, bromine) is introduced into these combustion processes, the unintentional creation of highly toxic dioxins such as PCDD and PBDD occurs. In this way even non-hazardous waste can pose a significant human health risk depending on how it is disposed. Polyvinyl chloride (PVC) plastics and materials containing brominated flame-retardants (as well as other sources of halogens), in particular, require special attention.

Hazardous waste management in LMICs is not well characterised, though co-mingling of waste streams is broadly practiced. In the absence of professional hazardous waste disposal options, the responsibility of proper disposal of medical waste falls largely on healthcare facility operators. Most hazardous waste generated in these settings is biologically versus chemically contaminated. Accordingly, disposal practices tend to focus on biologically contaminated waste, with the most widely practiced medical waste disposal option in LMICs being high-temperature thermal destruction (i.e. burning).

Mercury-containing wastes

Uncontrolled burning is not a sound management of mercury waste. It is an element and cannot be created or destroyed. It poses a health risk primarily because it is disassociated and freely circulating in the environment. As such mercury wastes can be responsibly disposed of in a manner consistent with the Basel Convention using two principal methods. In the first, it can be stabilised with sulphide (forming HgS) and disposed of in a specially engineered landfill. In the second it can be solidified and stored deep underground.[33] High-income countries take different approaches depending on their capacity and other concerns, with some handling it domestically and others exporting it in a manner consistent with the relevant conventions. In practice, it is likely that most mercury contaminated wastes in LMICs are incinerated, stored in ‘temporary’ storage indefinitely, or co-mingled with other solid waste streams.

Transitioning healthcare facilities away from mercury-added medical measuring devices will result in long-term reductions of mercury-contaminated waste streams. However, it will also introduce important considerations in the near term, including the disposal of a possible increased rate of mercury-contaminated wastes generated from any expedited transition. This could occur as facilities prematurely dispose of mercury-added equipment in the process of making upgrades. Likewise, end-of-life implications for mercury alternatives should be considered. To the extent that these devices contain PVC components, flame retardants, or other hazardous chemicals (e.g. phthalates) they should be handled accordingly. Considerations also have to be made for any implications of the current COVID-19 pandemic. Patient care in this case is a heavy generator of waste, including discarded personal protective equipment (PPE) and increased use and disposal of thermometers. PPE commonly contains PVC elements (e.g. face shields) as do thermometers. A number of agencies have made significant progress in assisting LMIC healthcare facilities with improving waste management practices. WHO has produced extensive guidance on waste management more generally and mercury specifically.[34] UNEP, UNDP and others regularly generate relevant reports and guidance.[35] Many of these guidance documents will be immediately relevant to the proposed project.

Regulatory context

Healthcare waste management is governed by a suite of international, national and subnational (e.g. provincial, municipal) regulatory frameworks. At the international level, relevant global and regional agreements, including the Basel, Minamata, Stockholm, and Bamako (in Africa) Conventions, oblige Parties to meet certain minimum waste management requirements. The Conventions tend to focus on practices that minimize transboundary concerns, such as those generated by the inadvertent creation of persistent organic pollutants (POPs) or poor management of global pollutants. To help countries meet these requirements, UN agencies and others have created a number of technical guidance documents, some of which are mentioned above.

Each country has its own national legislation regulating the management of healthcare waste. WHO has provided guidance on principles that might outline some of these laws, which still do not exist in many countries.[36] Most LMICs that have adopted laws have only done so recently and they tend not to be uniformly or consistently applied across healthcare centres.[37] In those countries that do not have specific legislation, healthcare waste management tends to be governed by rules or regulations of other broader laws.

As part of the development of the PIF, a cursory review of the relevant legal framework in each country was conducted. The list below is not exhaustive and will be expanded and improved during the PPG with assistance of local stakeholders. The following laws and regulations have been identified as immediately relevant to the project as part of the preliminary review:

Country	Relevant Laws and Regulations
Armenia	National Plan and National Strategy on Waste Management (2011) Decision on the necessary measures for collection and treatment of biowaste, criteria and deadlines for their reduction (2014) National Strategy on Integrated Waste Management (2018-2030) (2018) Regulation on hospital waste management (2010) Law No. 27/2016 On chemicals management Law No. 10 463, dated 22/09/2011 On integrated waste management Law No. 10 431, dated 09/06/2011 On environmental protection Law No. 10 237, dated 18/02/2010 On the safety and health at work
Burkina Faso	Law n ° 23-94 / ADP of May 19, 1994 Promulgating the Public Health Code Law No. 022-2005 / AN of May 24, 2005 of the Public Hygiene Code Law No. 017-2014 / AN of May 20, 2014 prohibiting the production, import, marketing and distribution of non-biodegradable plastic packaging and bags
India	Bio-Medical Waste Management Rules, 2016, amended 2018 Plastic Waste (Management and Handling) Rules, 2011. Plastic Waste Management Rules, 2016. The Bio-Medical Waste (Management and Handling) Rules, 1998
Montenegro	Law on Waste Management ("OG of MNE", No. 064/11, 039/16)

gro	Decree on the procedure for establishing a system for collection and treatment of electrical and electronic waste (“OG of MNE”, No. 24/12) Rulebook on the limit values of the hazardous substances in electrical and electronic equipment ("OG of MNE", No. 067/18) Law on Environment, (Official Gazette of Montenegro 52/16) Rulebook on criteria, method and treatment of medical waste (Official Gazette of Montenegro 4 9/12) Rulebook on waste classification and waste catalogue (Official Gazette of Montenegro 059/13, 0 83/16)) Rulebook on the methods of testing hazardous properties of waste (Official Gazette of Montene gro 037/18)
Uganda	The National Environment (Audit) Regulations; N0. 45 of 2020 The National Environment (Management of Ozone Depleting Substances) Regulations; N0. 48 of 2020 The National Environment (Waste Management)Regulations; N0. 49 of 2020 The Strategic Environment Assessment Regulations, N0. 50 of 2020

Table 1. Identified relevant laws and regulations in the target countries.

<u>Baseline by Country</u>

The annual amount of mercury (in kilograms) procured in thermometers and sphygmomanometers was used as the baseline for project. At the time of submission, Minamata Initial Assessments (MIAs) had been completed in Albania, Burkina Faso and Uganda only and were pending from Montenegro and India. Preliminary data from Montenegro was provided to the project on an informal basis.

MIAs collect data on the number of medical thermometers and often the number of manometers in a given country, however the latter is rarely disaggregated based on the proportion used in medical settings. [38] Additionally the total amount of mercury (in grams) contained in these devices in not necessarily reported in all cases. Accordingly a number of baseline values had to be imputed based on the existing data. These estimates will be improved during the PPG phase through stakeholder interviews and further analysis. The table below presents baseline data for the project by country.

Country	MIA	Toolkit Level	Hg procured annually in thermometers (kg)	Hg procured annually in sphygmomanometers (kg)
Albania	http://www.mercuryconvention.org/Portals/11/documents/MIAs/Albania-MIA-2018.pdf	2	249	0
Burkina Faso	http://www.mercuryconvention.org/Portals/11/documents/MIAs/Burkina-Faso-MIA-2018-FR.pdf	1	1,524	293
India	Not yet available	No data	1,621	1,621
Montenegro	Not yet available	1	4	1
Uganda	http://www.mercuryconvention.org/Portals/11/documents/MIAs/Uganda-MIA-2018.pdf	2	21	26

Table 2. Baseline by country. Estimated amount of mercury (kg) in medical devices procured annually in the project countries.

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Associated baseline projects

GEF projects

The GEF has supported a number of projects addressing issues in the area of healthcare waste management including one in a country covered by this project (India). The following two projects have included signrficant mercury-added medical devices components:

· GEF 1802 – “Demonstrating and Promoting Best Techniques and Practices for Reducing Health-care Waste to Avoid Environmental Releases of Dioxins and Mercury” in India (GEF-3; IA: UNDP);

· GEF 4611 – “Reducing UPOPs and Mercury Releases from the Health Sector in Africa” (GEF-5; IA: UNDP);

In addition, one other project is currently in the PPG having had the concept approved on 20 November 2019 (GEF 10349). The project ‘Demonstration of phase-out of mercury-containing medical thermometers and sphygmomanometers and promoting the application of mercury-free alternatives in medical facilities in China’ will be executed over 60 months and supported with USD 16 million in GEF resources. The project structure of 10349 is analogous to that proposed here, having included

outputs related to improved procurement, support for manufacturers, and the responsible management of mercury-contaminated wastes. This shared approach will facilitate knowledge sharing across projects as lessons learned could be immediately applicable. China is the world's largest manufacturer of mercury-added medical devices followed by India. The outcomes of each of these projects could therefore influence each other as markets potentially shift in response to project activities. In this way, the existence of 10349 should form a key consideration of the project baseline.

Non-GEF projects

Besides WHO, a leading actor in this area has been the international NGO Health Care Without Harm (HCWH). HCWH has worked in several of the target countries on mercury phase-outs in medical measuring devices.

Much of the baseline data for India is drawn from a 2009 report completed by the Indian NGO ToxicsLink "Moving Towards Mercury-Free Health Care: Substituting Mercury-Based Medical Devices."

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c) The proposed alternative scenario with a brief description of expected outcomes and components of the project

The overall project objective of global importance is to prevent the exposure of humans and the environment to mercury and its waste through the establishment and implementation of a road map for a significant reduction in use and emissions/releases.

The project will be couched in the WHO step-by-step guidance and will support the development of national health system-wide strategies to phase-out the manufacture and procurement of mercury-added thermometers and sphygmomanometers (blood pressure measuring devices) used in healthcare, in 5 countries from 3 regions.[39] It will also involve practical demonstration of the switch to mercury-free alternatives in at least 3 countries of the 5 targeted. In so doing it will strengthen collaboration between ministries of health and the environment. The theory of change is in figure 2 below and the supporting problem and solution tree are attached as annex.

The proposal has been developed under 4 components. The first involves the development of strategies based on detailed country assessment and best practices. The second involves the piloting of those strategies, while the third covers knowledge management. Finally, a fourth component covers monitoring and evaluation. The components are outlined below.

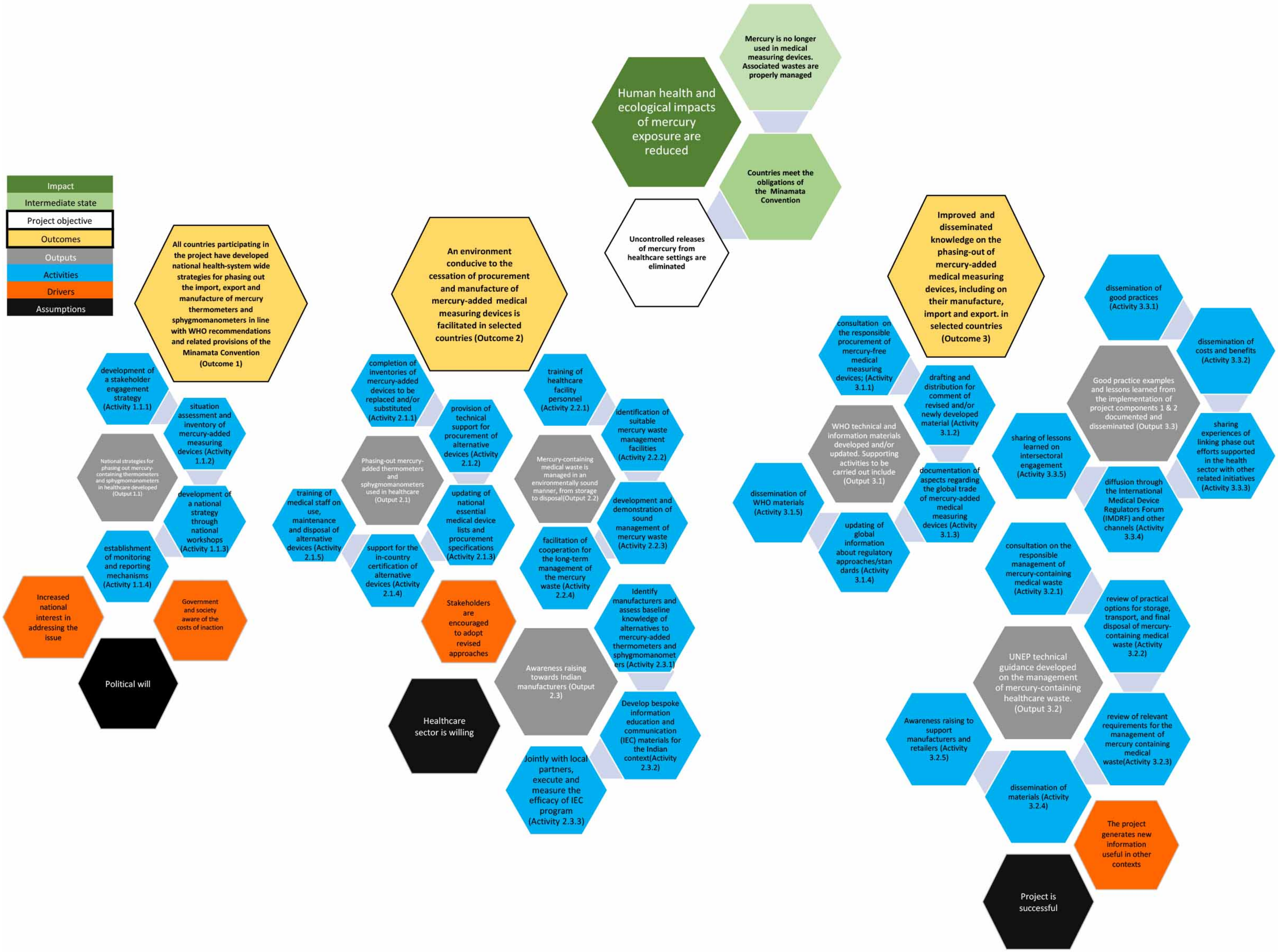

Figure 2: Theory of change

Component 1: Development of national health system-wide strategies for phasing out the procurement and manufacture of mercury thermometers and sphygmomanometers in line with WHO recommendations and related provisions of the Minamata Convention.

Outcome 1: All countries participating in the project have developed national health-system wide strategies for phasing out the procurement and manufacture of mercury thermometers and sphygmomanometers in line with WHO recommendations and related provisions of the Minamata Convention.

Output 1.1: National strategies for phasing out mercury-containing thermometers and sphygmomanometers in healthcare developed. Supporting activities to be carried out include:

- 1.1.1 development of a stakeholder engagement strategy;
- 1.1.2 carrying out of a situation assessment and inventory of mercury-added measuring devices, drawing on findings of Minamata Initial Assessment activities as applicable;
- 1.1.3 development of a national strategy (that includes addressing waste as well as broader water, sanitation and hygiene [WASH] issues) in consultation with relevant stakeholders, through national workshops;
- 1.1.4 establishment of monitoring and reporting mechanisms linked to the national strategy;
- 1.1.5 capacity building of relevant government stakeholders.

Component 2: Implementation of national strategies to phase out procurement and manufacture in all project countries, and demonstrations of a phase out in use in at least 3 countries.

Outcome 2: An environment conducive to the cessation of procurement and manufacture of mercury-added measuring devices is facilitated in selected countries.

Output 2.1: Phasing-out mercury-added thermometers and sphygmomanometers used in healthcare, from procurement to the safe and environmentally sound interim-storage of mercury-containing wastes. Supporting activities to be carried out include:

- 2.1.1 completion of site/facility-specific inventories of mercury-added devices to be replaced (in line with Minamata Convention obligations) and/or substituted;
- 2.1.2 provision of technical support for procurement of alternative devices;
- 2.1.3 updating of national essential medical device lists and procurement specifications, if applicable;
- 2.1.4 support for the in-country certification of alternative devices;
- 2.1.5 training of medical staff on use, maintenance and disposal of alternative devices;
- 2.1.6 training of relevant regulatory and compliance staff;
- 2.1.7 development and execution of awareness program for the general public.

Output 2.2: Mercury-containing medical waste is managed in an environmentally sound manner, from storage to disposal. Supporting activities in this regard to be carried out include:

- 2.2.1 training of waste managers on the handling and disposal of mercury-containing wastes following guidance developed under the GEF programme on mercury in healthcare;
- 2.2.2 identification of suitable mercury waste management facilities;
- 2.2.3 development and demonstration of sound management of mercury waste in relevant countries;
- 2.2.4 facilitation of cooperation between healthcare providers, hazardous waste management companies, and government for the long-term management of mercury waste.

Output 2.3: Awareness raising towards Indian manufacturers

- 2.3.1 Identify manufacturers and assess baseline knowledge of alternatives to mercury-added thermometers and sphygmomanometers;
- 2.3.2 Develop bespoke information education and communication (IEC) materials for the Indian context to include environmental, economic, health benefits aspects;
- 2.3.3 Jointly with local partners, execute and measure the efficacy of IEC program.

Component 3: Knowledge management

Outcome 3: Improved and disseminated knowledge on the phasing-out of mercury-added medical measuring devices, including on their manufacture and procurement.

Output 3.1: WHO technical and information materials developed and/or updated. Supporting activities to be carried out include:

- 3.1.1 consultation of executing partners, key stakeholders, and relevant experts on the responsible procurement of mercury-free medical measuring devices;
- 3.1.2 drafting and distribution for comment of revised and/or newly developed material;
- 3.1.3 documentation of aspects regarding the global trade of mercury-added medical measuring devices;
- 3.1.4 updating of global information about regulatory approaches/standards for mercury-free thermometers and sphygmomanometers used in healthcare;
- 3.1.5 dissemination of WHO materials through WHO networks and the WHO website.

Output 3.2: UNEP technical guidance developed on the management of mercury-containing healthcare waste. Supporting activities to be carried out include:

- 3.2.1 consultation of executing partners, key stakeholders, and relevant experts on the responsible management of mercury-containing medical waste;
- 3.2.2 review of practical options for temporary storage in-country, transport, final disposal of mercury-containing medical waste and review of related protective equipment;
- 3.2.3 review of relevant requirements for the management of mercury containing medical waste, including convention obligations;
- 3.2.4 dissemination of materials through UNEP website and partners, including through the UNEP Global Mercury Partnership;
- 3.2.5 Awareness raising to support to manufacturers and retailers identify, produce and (for retailers) purchase alternatives to mercury thermometers and sphygmomanometers.

Output 3.3: Good practice examples and lessons learned from the implementation of project components 1 & 2 documented and disseminated, including through WHO channels and the UNEP Global Mercury Partnership. Illustrative topics to be addressed in this regard may include:

- 3.3.1 dissemination of good practices in the regulation and procurement of alternatives, and the phasing out of manufacturing of mercury-added medical measuring devices;
- 3.3.2 dissemination of costs and benefits associated with the phasing out of mercury thermometers and sphygmomanometers used in healthcare;
- 3.3.3 sharing experiences of linking phase out efforts supported in the health sector with other related initiatives;
- 3.3.4 diffusion of country practices through the International Medical Device Regulators Forum (IMDRF) and other channels;
- 3.3.5 sharing of lessons learned on intersectoral engagement and the coordination required for this.

Component 4: Monitoring and evaluation

Outcome 4: Project results are available nationally and shared with other countries participating in this project, and globally.

Output 4.1: Monitoring and evaluation activities carried out as per the GEF requirements.

d) alignment with GEF focal area and/or Impact Program strategies

The project aims to assist the target countries in meeting their obligations under the Minamata Convention by eliminating the use of mercury-added medical measuring devices. Four of the five target countries are required to phase out these devices, covered under Article 4 of the Convention, by 2020 (India has an exemption until 2025). All except India are therefore remiss in meeting their Convention obligations, underlining the urgency and importance of the project. As the primary funding mechanism for the Minamata Convention, the GEF’s objectives directly align with these targets. Specifically the project is consistent with GEF focal area CW-1-1 ‘Strengthen the sound management of industrial chemicals and their waste through better control, and reduction and/or elimination.’

Component 1 deals with development of bespoke national strategies for the phasing out of mercury-added medical measuring devices. The WHO has developed broad guidance that must be actively adapted to individual country contexts. The resulting strategies will be implemented through activities carried out as part of Component 2 and more broadly shared as part of Component 3 on knowledge management.

e) Incremental/additional cost reasoning and expected contributions from the baseline, the GEFTF, LDCF, SCCF and co-financing

Paragraph 7 of Article 13 of the Minamata Convention obligates GEF resources to countries' compliance efforts. Specifically it defines "new, predictable, adequate and timely financial resources to meet costs in support of implementation of [the] Convention" and states that "[the GEF] shall provide resources to meet the agreed incremental costs of global environmental benefits."

The project will intervene directly in existing procurement efforts in the healthcare sector. The substantial resources that are currently allocated here for purchasing mercury-added medical measuring devices will be redirected toward more sustainable alternatives. In this way the project's relatively small investment will be immediately amplified through other pre-existing mechanisms. The project will also invest directly in improving waste management practices. Here too, the approach will largely involve realigning and improving existing processes, thus implicitly leveraging 'investment.'

In the case of India, the project will work with manufacturers to raise awareness about transition away from mercury-added product lines. A study carried out of such a transition by a US manufacturer found that the initial investment was returned within a year, owing largely to reduced compliance and insurance costs.[40] As the domestic Indian market shifts more quickly away from mercury as a result of the project, these manufacturers may be able to eliminate the costly enterprise of maintaining two parallel product lines (mercury-added and mercury-free). To the extent that this occurs, these financial gains would be directly attributable to the project.

Co-financing for the project is expected to be substantial and draw from national healthcare budgets, including those of public hospitals and ministries of health. Additional co-financing will be invested by individual manufacturers in India. Finally both the implementing and executing agencies will provide in-kind support.

f) Global environmental benefits (GEFTF) and/or adaptation benefits (LDCF/SCCF)

Mercury is released from thermometers and sphygmomanometers through inadvertent rupture and poor waste management practices. The project will reduce the total amount of mercury-added medical devices in use in at least three of the targeted countries, thereby substantially reducing the frequency and likelihood that such ruptures will occur. Free mercury in the environment cycles globally through atmospheric transport and other mechanisms. Thus by reducing releases in these three countries, the project will result in immediate global environmental benefits.

The project will also improve healthcare waste management practices. At present mercury-added medical measuring devices are inadequately separated from other waste streams and contribute to total mercury releases. In addition, materials containing halogenated chemicals (i.e. containing bromine, chlorine, fluorine) are intermingled with other wastes and incinerated. These highly reactive chemicals can create dioxins and dioxin-like compounds when combusted in the presence of other common materials. The project will encourage more responsible waste management practices and therefore reduce the Toxic Equivalency (TEQ) of waste incineration. Dioxin concentrations are expressed in units of TEQ which is a measure of the mass concentration and a given dioxin weighted by its specific Toxicity Equivalence Factor (TEF). TEFs are benchmarked against the most toxic known dioxin, 2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8-TCDD), and can range from 1 to 0.00001.[41]

With the exception of India, which has an exemption until 2025, each of the countries in the project is obligated to have phased out mercury importation by 2020, before the project start date.[42] Thus GEBs are calculated based on procurement from domestic stocks only. Because limited data are available on the quantity of these stocks they are approximated based on known import values from previous years. The estimates presented herein will be improved during the PPG phase.

The project will wind-down procurement of mercury-added medical measuring devices at a rate of 20 % per year from the baseline resulting in a complete phase-out of these devices with the project's time frame. This phased approach will result in a total of 23,956 kg mercury procurement avoided (sub indicator 9.2). This estimate is based on certain assumptions, explained below.

We calculate that the target countries procure thermometers and sphygmomanometers containing approximately 3,418 kg Hg and 1,941 kg Hg, respectively, on an annual basis. This work will take place in three countries as part of Component 2. For the purpose of determining the project's global environmental benefits, we utilize the values for current annual procurement in Albania, India, and Uganda. These countries procure an estimated total amount of 3,537 kg Hg in mercury-added medical devices per year.

Assuming an annual replacement amount of 707 kg (3,537 kg/ 5 years), and an annual phase-out of 20 %, the project will phase out 707 kg in year one, 1,415 kg in year 2, 2,122 kg in year 3 and so on. The net result of these activities will be a total of 10,610 kg of mercury procurement avoided. We further estimate that through dissemination activities, procurement in the remaining 2 project countries will reduce at a rate of 5 % per year for a net avoidance of 1,367 kg. Thus the total amount of Hg procurement avoided will be 11,978 kg. Figure 1 provides a summary for the three countries targeted as part of Component 2.

The project will also endeavour to improve how mercury waste is handled. Assuming the same 20 % annual uptake of improved waste management practices, the project will result in a proportionate 11,978 kg of mercury managed soundly. Thus the project's total contribution to indicator 9.2 is calculated as 23,956 kg Hg.

Sub-indicator 9.6 estimates include the total mass of equipment containing mercury. To calculate this value, we estimate the weight of a single thermometer as 15 grams and the weight of a single sphygmomanometer as 500 grams. Applying the same assumptions as above, this results in a total 98,358 kg Hg-contaminated material avoided.

Owing to the limited baseline data on TEQ at present, estimates of TEQ reductions are not provided here but are expected to be substantial. This is expected particularly in the context of increased PPE procurement during the COVID-19 pandemic.

These estimates are preliminary and based on the best available data. They will be improved through stakeholder engagement and data collection done as part of the PPG.

g) Innovation, sustainability and potential for scaling up

The present project represents progress against this issue in a broad and heterogenous geographic area. The five countries targeted are drawn from 3 continents and distinct in economic and social composition. Thus the lessons learned will potentially be widely applicable beyond on the project.

The general approach of the project will one of facilitating more responsible use of existing resources. From a procurement perspective, the proposed alternatives are more cost-effective over the medium term than mercury-added devices.[43] They are also safer, equally accurate, and more precise. Thus if the initial barriers are overcome, sustainability is built in to the project; there is no precedent (which could be identified) of a healthcare system regressing back to mercury-added devices. Likewise from a supply perspective, the manufacture of a mercury-free product line does not carry additional costs associated with the handling of hazardous materials. Manufacturers are also highly responsive to demand.

The project will target centralized procurement and will therefore immediately affect changes at scale. An effective knowledge management component will share lessons learned outside of the target countries facilitating changes beyond the project timeline and geography.

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[33] UNEP (n 21).

[34] WHO, *Developing National Strategies for Phasing out Mercury-Containing Thermometers and Sphygmomanometers in Health Care, Including in the Context of the Minamata Convention on Mercury: Key Considerations and Step-by-Step Guidance* (World Health Organization 2015); Yves Chartier and others, 'Safe Management of Wastes from Health Care Activities. 2nd Edition' [2014] Bulletin of the World Health Organization.

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[36] Chartier and others (n 36); WHO (n 36).

[37] Mustafa Ali and others, ‘Hospital Waste Management in Developing Countries: A Mini Review’ 581 <http://journals.sagepub.com/doi/10.1177/0734242X17691344> accessed 6 June 2020.

[38] In the countries covered by this project only the Uganda MIA provides an estimate of the number of medical sphygmomanometers in the country

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[40] Morose and Lindberg (n 27).

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1b. Project Map and Coordinates

Please provide geo-referenced information and map where the project interventions will take place.

Will be defined during PPG.

2. Stakeholders

Select the stakeholders that have participated in consultations during the project identification phase:

Indigenous Peoples and Local Communities

Civil Society Organizations Yes

Private Sector Entities Yes

If none of the above,please explain why:

Stakeholder engagement is critical to the success of the overall national strategy to phase-out mercury medical measuring devices. The extent to which the process is seen to be inclusive of the views and inputs of all relevant actors can influence the extent to which those actors feel ownership and responsibility for the delivery of specific interventions. As such, key stakeholders during the project identification phase include WHO Headquarters, Regional Offices, and Country Offices; UNEP and the UNEP's Global Mercury Partnership; the Minamata Convention Secretariat; the ministries of health and environment in Albania, Burkina Faso, India, Montenegro, and Uganda; and private sector manufacturers and suppliers of non mercury devices, either directly or through their associations.

In the PPG phase, an international stakeholder engagement strategy will be developed. Additional stakeholders that may be involved include international non-state actors, such as international NGOs and international professional societies (e.g. the World Medical Association, World Federation of Public Health Associations (WFPHA), and the International Medical Devices Regulators Forum (IMDRF)). IMDRF is a global network of medical devices regulators working to accelerate international medical device regulatory harmonization with key connections related to the procurement of non mercury devices. Private sector manufacturers and suppliers of non-mercury devices will be involved during project execution either directly or through their associations. These stakeholders will provide relevant information on the country-specific situations based on the estimated burden of mercury-added medical measuring devices in use in both private and public healthcare sectors as reported in each country's MIA; information about procurement possibilities for non mercury devices; the burden of existing mercury-containing waste that requires safe and environmentally sound interim-storage; and how best to disseminate information to other stakeholders, including the broader healthcare community.

At the national level, while the ministries of health will have a leading role to play in developing and implementing a phase-out strategy for mercury-containing medical measuring devices, contributions from the broader health sector, as well as other sectors and actors will also be needed in order to support strategy development and implementation. As such, during the early stages of executing Component 1, a national stakeholder engagement strategy will be developed by each project country, supported by WHO together with UNEP, as set out in the WHO step-by-step guidance for developing national strategies and drawing on effective practices demonstrated by other projects.[1] Stakeholder groups are expected to include representatives from: regulatory authorities, suppliers and manufacturers, hospital associations, public and private associations of health professionals, health care providers who would be the primary users of mercury-free devices, health care facility managers and their organizations, researchers from academia or national institutions, and relevant civil society of nongovernmental organizations. The task of developing a stakeholder engagement strategy (which would be an integral component of the overall national strategy) would likely be incumbent on the ministry of health representative(s) charged with overseeing the development an delivery of phase-out activities in the health sector.

Broader stakeholder groups identified during the PPG phase will remain engaged in relevant areas of the project implementation work.

With global and national level steering committees, national project coordinators in WHO country offices will provide support to the ministries of health for the organization of situation assessments and inventories of mercury-added medical measuring devices, drawing on findings of Minamata Initial Assessment activities. WHO will provide support to each country in the development of a national strategy that includes addressing mercury waste as well as broader water, sanitation, and hygiene (WASH) issues, through national workshops that include representatives of ministries of health, environment, and customs; representatives of hazardous waste management companies; representatives of major healthcare facilities; relevant experts on the responsible procurement of mercury-free medical measuring devices; device manufacturers in-country, and possibly device manufacturers from major non domestic points of manufacture/distribution if non mercury alternatives are not manufactured in the project country. Through teleconferences and workshops a core group of the aforementioned stakeholders will be engaged to contribute to WHO, UNEP, and the UNEP Global Mercury Partnership developing or updating, and disseminating technical guidance and information materials, including sharing information on providing support to producing companies and retailers to promote alternatives to mercury thermometers and sphygmomanometers.

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[1] WHO (n 36).

In addition, provide indicative information on how stakeholders, including civil society and indigenous peoples, will be engaged in the project preparation, and their respective roles and means of engagement.

Stakeholder	Role in the project preparation	Proposed engagement in project
International Governmental Organizations		
Minamata Secretariat	Consulted during project identification	Secretariat of the Minamata Convention on Mercury will provide available and updated information related to mercury-containing medical measuring devices
UNEP	Participated in consultation with national project partners, discuss co-finance contributions, and provide input into the project design. Lead the UNEP Global Mercury Partnership. Contribute to consultation with national project partners for their country projects.	UNEP Chemicals and Wastes Branch, which maintains a comparative advantage in management of Hg wastes, is the IA and responsible for delivery of the project.
UNEP Global Mercury Partnership	Participated during project identification, preparation, and execution including	The UNEP Global Mercury Partnership will provide targeted technical assistance and assist in identifying actions for mercury wa

	n, and execution including attending project formulation workshops. Provide information on baseline projects and co-financing partners. Already has an established roster of experts.	assist in identifying actions for mercury waste management and feasible remediation at identified contaminated sites in project countries. The Partnership has members in the following countries of the project: Burkina Faso (government), India, (NGO) Uganda (NGO). The Partnership Areas on product and waste have a pool of experts to be engaged during the project.
WHO	Executing Agency leading the planning of the project, leading the project design, development and execution arrangements.	WHO will be the EA. WHO, a UN specialized organization, is the directing and coordinating authority on international health work. WHO will provide support to ministries of health to promote regulatory action to phase out mercury medical measuring devices in line with the Minamata Convention, support health ministries to develop and implement strategies to change procurement practices, to disseminate technical guidance, and run the day to day project activities. The 67th World Health Assembly, through its Resolution no. WHA67.11 (2014) called upon its member states to sign, ratify, and implement the Minamata Convention on Mercury and to address the health aspects of exposure to mercury and mercury compounds through collaboration between health authorities, environment authorities, and others.
Government		
Ministry of Health and Ministry of Water and Environment **Uganda**	Consulted during project identification, preparation, and execution phases	Lead the national project steering committee and oversee the execution of national activities. The experience and lessons learned from the country will feed into sharing global knowledge and benefit other countries.

Ministry of Health and Ministry of Environment Burkina Faso	Consulted during project identification, preparation, and execution phases	Lead the national project steering committee and oversee the execution of national activities. The experience and lessons learned from the country will feed into sharing global knowledge and benefit other countries
Ministry of Health and Family Welfare and Ministry of Environment and Forests **India**	Consulted during project identification, preparation, and execution phases	Lead the national project steering committee and oversee the execution of national activities. The experience and lessons learned from the country will feed into sharing global knowledge and benefit other countries
Ministry of Health and Ministry of Tourism and Environment Albania	Consulted during project identification, preparation, and execution phases	Lead the national project steering committee and oversee the execution of national activities. The experience and lessons learned from the country will feed into sharing global knowledge and benefit other countries
Ministry of Health and Ministry of Sustainable development and Tourism **Montenegro**	Consulted during project identification, preparation, and execution phases	Lead the national project steering committee and oversee the execution of national activities. The experience and lessons learned from the country will feed into sharing global knowledge and benefit other countries
International non-state actors		
International professional societies (e.g. WMA, WFPHA, and IMDRF). etc.)	Consulted during project preparation and execution phases	Provide information in the PPG phase and provide support in the execution of activities on request
Other National Stakeholders		
Uganda Regulatory authorities; suppliers; hospital associations; associations of health professionals; healthcare providers; healthcare	To be involved during project execution	Engage in project activities and ensure national ownership

facility managers; academia, relevant civil society or NGOs		
Burkina Faso Regulatory authorities; suppliers; hospital associations; associations of health professionals; healthcare providers; healthcare facility managers; academia, relevant civil society or NGOs	To be involved during project execution	Engage in project activities and ensure national ownership
India Regulatory authorities; suppliers and manufacturers; hospital associations; associations of health professionals; healthcare providers; healthcare facility managers; academia, relevant civil society or NGOs	To be involved during project execution	Engage in project activities and ensure national ownership
Albania Regulatory authorities; suppliers; hospital associations; associations of health professionals; healthcare providers; healthcare facility managers; academia, relevant civil society or NGOs	To be involved during project execution	Engage in project activities and ensure national ownership
Montenegro Regulatory authorities; suppliers; hospital associations; associations of health professionals; healthcare providers; healthcare facility managers; academia, relevant civil society or NGOs	To be involved during project execution	Engage in project activities and ensure national ownership

Table 3. Stakeholders identified at the PIF stage

3. Gender Equality and Women's Empowerment

Briefly include below any gender dimensions relevant to the project, and any plans to address gender in project design (e.g. gender analysis).

The healthcare sector globally is overwhelmingly female (67 %), though men tend to occupy more senior positions. In Africa, for example, only 28 % of physicians are female, while 65 % of nurses are. In the WHO South-East Asia region (which includes India) 39 % of physicians are female, compared with 79 % of nurses.[1] These disparities reflect gender inequalities more broadly in the regions.

The UNDP gender development index is a metric that endeavours to combine the relative wellbeing of women with regard to health, knowledge, and living standards. Of the 166 countries for which a ranking was available in 2018, Albania ranked 68th; Burkina Faso, 137th; India, 154th; Montenegro, 77nd; and Uganda, 145th.[2] A related but distinct UNDP metric, the gender inequality index is intended to measure women's reproductive health, empowerment and the labour market. Of the 161 countries for which a ranking exists for 2018, Armenia ranked 51th; Burkina Faso, 147nd; India, 122st; Montenegro, 27th; and Uganda, 127th.[3] Thus the gender context in the five target countries is a major consideration, with 3 of the 5 being in the lower quartile of equality and all in the lower 75 %. It is also highly variable with each country necessarily requiring a bespoke approach.

With regard to political leadership, 29.3 % of Albania's parliament in 2018 was female, placing it 53rd out of 193 countries ranked by the Inter-Parliamentary Union. Burkina Faso, India, Montenegro, and Uganda's parliaments (or equivalent) were 13.4 %, < 12 %, 23.5 % and 34.9 % female, respectively. For context, the US was less than 25 % female while the UK was less than 30 % female. The most female legislative body in 2018 was Rwanda's Chamber of Deputies (61.3 %). Globally, only 3 of the 193 countries evaluated had legislative bodies that we more than 50 % female.[4]

The WHO has defined gender as major structural determinant of social inequality which in turn manifests in unequal health outcomes.[5] Physiological distinctions between women and men also play a role, particularly in the case of chemicals exposure. Women tend to have higher percentages of body fat, for instance, making them more susceptible to the deleterious effects of lipophilic chemicals like PCBs and mercury.[6]

As part of the PPG the project will develop a gender action plan which will be linked to the results framework. In so doing, progress against gender indicators will be tied to overall project milestones and, subsequently payments. A gender specialist will be contracted to ensure gender considerations are addressed consistently and adequately across the project. Materials will be reviewed by the gender specialist and all indicators, where applicable, will be gender disaggregated.

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[1] Boniol and others (n 1).

[2] UNDP, 'Human Development Data (1990-2018) | Human Development Reports' <http://hdr.undp.org/en/data#> accessed 12 February 2020.

[3] UNDP (n 48).

[4] Inter-Parliamentary Union, 'Women in Parliaments: World Classification' <http://archive.ipu.org/wmn-e/classif.htm> accessed 11 February 2020.

[5] Michael Marmot and others, 'Closing the Gap in a Generation: Health Equity through Action on the Social Determinants of Health' (2008) 372 The Lancet 1661.

[6] UNDP, 'Chemicals and Gender' <http://www.undp.org/content/undp/en/home/librarypage/environment-energy/chemicals_management/chemicals-and-gender.html>.

Does the project expect to include any gender-responsive measures to address gender gaps or promote gender equality and women empowerment? Yes

closing gender gaps in access to and control over natural resources;

improving women's participation and decision-making; and/or Yes

generating socio-economic benefits or services for women.

Will the project's results framework or logical framework include gender-sensitive indicators?

Yes

4. Private sector engagement

Will there be private sector engagement in the project?

Yes

Please briefly explain the rationale behind your answer.

All mercury-added and mercury-free medical measuring devices in the target countries are manufactured in the private sector. With regard to procurement, these actors will be engaged to provide competitive pricing of provision and maintenance of alternatives and any necessary training. They will also be engaged to ensure adequate supply to meet the vast needs of public healthcare systems. With regard to manufacture, these actors will be engaged to ensure they have access to any technical or financial resources required to transition to mercury-free product lines. Finally with regard to waste management considerations, to the extent that private sector actors are involved in the management of healthcare waste, the project may provide training and assistance. Specific private sector roles in each country will be defined as part of the PPG.

In the case of India, significant progress has been made in phasing out mercury-added medical devices in the public sector, particularly in urban areas. Project activities will therefore largely target the private sector, including those activities related to procurement, manufacture and waste management.

5. Risks to Achieving Project Objectives

Indicate risks, including climate change, potential social and environmental risks that might prevent the Project objectives from being achieved, and, if possible, propose measures that address these risks to be further developed during the Project design (table format acceptable)

Risk	Risk ranking	Mitigation measures
Operational/delivery risks		
Political instability and shifting priorities	Medium	The institutionalization of the project and the National Coordination Committee will be encouraged, limiting the its reliance on any one or set of individuals who may susceptible to replacement due to political changes.
National support is not provided or is not adequate for project needs	Medium	Have clear country and co-finance agreements and ensure country commitments to the established agreements. A detailed survey of available capacity will be conducted during the PPG
Inadequate supply of mercury-free devices	Low	Market survey in each of the countries during PPG to ensure adequate supply.
Lack of transparency in financial management and distribution	Low	Clear terms or reference in advance of work. Regular reporting of disposed funds against activities completed. Execution coordinated via EA to increase scrutiny of financial transactions.
Increased COVID-19 exposure risk to project staff and targeted communities	Medium	Best practices with regard to personal hygiene, PPE, social distancing and other measures will followed by project staff. Compliance will be monitored by the project manager.
Limited mobility of project team due to the ongoing COVID-19 pandemic inhibits project execution	High	The project would begin in 2022. In the event that the current situation has not improved and movement continues to be equally restricted (domestically and internationally) the project will be adjusted accordingly, including utilising remote guidance of international experts and an increased reliance on local experts. In either case, remote tools will be central to implementation. Work during the PPG will be conducted throughout 2021 before widespread vaccination is likely. During the PPG phase the risk of COVID-19 impacting on planning for the project will also will be mitigated due to WHO's presence in each country as well as by utilizing tools for virtual meetings for collaborative planning discussions with the countries and partners.
Lack of availability of healthcare staff due to COVID-19	Medium	The national project coordinators to be recruited by WHO through the project will be briefed, prepared and expected to take on greater coordinating and liaising responsibilities with Ministries of Health in the respective countries in case of changing responsibilities of Ministry staff due to the pande

		mic.
Demand for thermometers due to COVID-19 prohibitively incre ases replacement price	Medium	The project would begin in 2022 providing time for manufacturers to meet burgeoning demand and for prices to stabilise.
Environmental safeguard risks		
Accident or spill during disposa l	Medium	Have in place adequate health and safety plans, PPE and spill response pl ans and teams.
Enthusiastic uptake results in u nmanageable quantities of was te	Medium	Closely link procurement with waste management to anticipate increases. Develop a waste management infrastructure capable of rapid scaling.
Social risks		
Poor uptake of alternatives	Medium	The project will refer to successful approaches from other countries when developing interventions. Careful partner vetting to ensure sufficient defer ence to the obligations of the Convention and authority to set policy
Climate change risks		
Enthusiastic procurement resul ts in increased waste and attrib utable GHG emissions	Low	The project will encourage responsible procurement and disposal. Waste management activities will consider climate change risks associated with waste management.
Increased volatility of poorly di sposed Hg wastes due to clima te change (i.e. increased ambie nt temperatures and forest/ bru sh fires)	Low	Waste management activities will consider climate change risks associate d with waste management.
Climate-induced increases in in fectious diseases increases de mand for thermometers	Medium	Changes in disease patterns and subsequent increases in thermometer de mand represent both opportunities and risks to the project. Increased de mand could increase price and therefore encourage the continued use of Hg-added devices based on their lower sticker price. Conversely, increased international support (i.e. aid) coupled with demand could offer an opportu nity to encourage more responsible procurement. The project will conduct a more thorough evaluation of these risks and opportunities during the PP G.

Table 4. Identified social, economic and environmental risks and their impact level and mitigation measures

6. Coordination

Outline the institutional structure of the project including monitoring and evaluation coordination at the project level. Describe possible coordination with other relevant GEF-financed projects and other initiatives.

ıplementing Agency (IA): This project will be implemented by UNEP. UNEP will be responsible for the overall project supervision, overseeing the project progress through the onitoring and evaluation of project activities and progress reports. It will be responsible for quality assurance procedures, organize contracting with the Executing Agency, ıprove progress reports and clear disbursement. The IA will also monitor progress to ensure the quality of outputs. It will report the project implementing progress to the EF and will take part in the Project Steering Committee (PSC). UNEP will closely collaborate with the EA and provide it with administrative support in the implementation of e project. UNEP has extensive experience minimizing Hg use and encouraging the responsible management of Hg wastes. UNEP leads the Global Mercury Partnership.

ecuting Agency (EA): WHO will be the executing agency for this project with targeted technical inputs from UNEP Global Mercury Partnership. As EA, the key roles of WHO clude:

Establishing and housing the project executing unit (PEU)

Perform day-to-day tasks and monitoring of planned activities. WHO will report to the IA and provide narrative and financial updates

Lead the Global Project Steering Committee (PSC)

Recruit and manage national project coordinators (NPC)

oject Executing Unit: The PEU (housed at WHO) will be staffed by a Project Manager. The role of the PEU is to:

Ensure project execution (all technical aspects of project execution)

Ensure project governance and oversight of the financial resources from GEF investment

Provide staff time and expertise in guiding and advancing the project

Sharing all achievements and project products/outputs with stakeholders

Supervise respective consultants and project partner organizations to deliver against their contracts and in time

Organize the PSC meetings and serve as its lead

Manage and implement the project results and output level M&E framework, to evaluate project performance

Manage the flow of information from the field and produce periodic monitoring reports

ırgeted Technical assistance (TTA): TTA will be provided by the Global Mercury Partnership, in particular through the Secretariat, and the Partnership Areas on products and aste. The role of the TTA entity is to:

Provide bespoke guidance to project partners on implementation

Share best practices from other projects and regions

Identify, as necessary, additional relevant expertise

Be available for consult on a specific technical issues

obal Project Steering Committee: The PSC's membership includes the IA, EA, focal points of the country projects, and other relevant national and international akeholders. The PSC will meet four times over the course of the project. Where feasible and appropriate, meetings will be convened back to back with other relevant events held via videoconference as needed and appropriate, to contain costs.

SC meetings will be organized by WHO. The role of the PSC is to:

Provide overall guidance and ensure coordination among all participating organizations

Approve the annual work plan and budget

Oversee any corrective actions needed

Enhance synergy between the GEF project and other on-going initiatives globally and nationally

-

National Project Steering Committee: The national project steering committees in each country will be co-led by ministry of health and ministry of environment. The committee will also include representatives from other relevant ministries, civil society organizations, experts that work on mercury and medical measuring devices, the National Project Coordinator (to be recruited by WHO), and the private sector. The national project steering committee will meet every 6 months or on an as-needed basis to:

- Provide overall guidance and ensure coordination among all participating organizations, sectors, and entities nationally
- Approve the annual work plan
- Oversee any corrective actions needed
- Enhance synergy between the GEF project and other on-going initiatives nationally

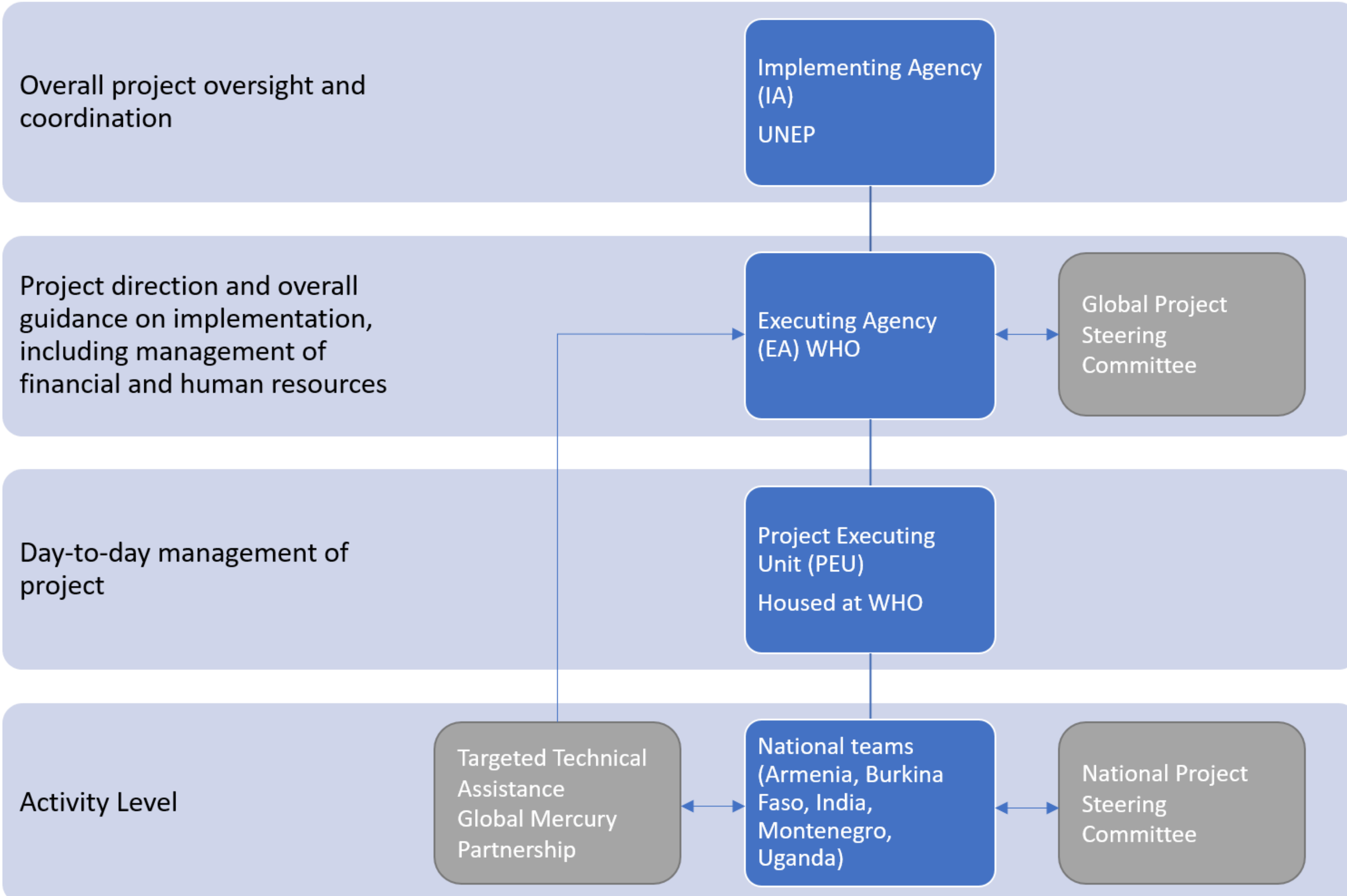

Figure 3. Institutional arrangements and coordination

In addition to those immediately involved with the execution of the present project, the project team will coordinate with other project currently in development, including one by the Waste Partnership Area of the UNEP Global Mercury Partnership on phasing out mercury from medical devices in Asian countries and GEF-funded UNDP -implemented project in China: GEF 10349 – “Demonstration of production phase-out of mercury-containing medical thermometers and sphygmomanometers and promoting the application of mercury-free alternatives in medical facilities in China.” (GEF-7; IA: UNDP). Uganda). Further detail on the exchange of information with 10349 is provided below.

7. Consistency with National Priorities

Is the Project consistent with the National Strategies and plans or reports and assesments under relevant conventions

Yes

If yes, which ones and how: NAPAs, NAPs, ASGM NAPs, MIAs, NBSAPs, NCs, TNAs, NCSAs, NIPs, PRSPs, NPFE, BURs, INDCs, etc

This project supports the national priorities of the target countries, particularly those related to the Minamata Initial Assessments (MIA). These relationships are described below organized alphabetically by country.

Albania

Albania ratified the Minamata Convention in May 2020. From 2010–2019 Albania imported an average of > 300,000 liquid filled thermometers per year. These trade data are not disaggregated by the type of liquid (e.g. alcohol, mercury) or use (e.g. industrial, medical) but the 2020 Albania MIA estimates that perhaps > 1/3 of these were mercury-added medical devices. As a category, intentional mercury use in products is responsible for 76 % of annual mercury releases in Albania. Thermometers are the by far the largest contributor to this category responsible for nearly 6 times the amount of Hg releases annually than electrical switches, the next largest contributor. The Albania MIA notes that Hg sphygmomanometers have been successfully phased.

Accordingly, the MIA states that that 'reducing mercury in products is the most effective means to decrease the emissions into various media, particularly from the mercury containing waste streams.' And further that following the results of mercury inventory, it is important to develop a national strategy and relevant action plan to identify and protect populations at risk regarding mercury and its compounds, particularly vulnerable populations.' Thus the proposed project is fully consistent with the priorities set out in the MIA.

-

Burkina Faso

Burkina Faso ratified the Minamata Convention in April 2017. The Burkina Faso MIA outlines the '[establishment of] an environmentally sound management system for municipal waste, biomedical waste and hazardous waste containing mercury' as a national priority. Moreover it notes that 'products containing added mercury are one of the major sources of mercury input into Burkina Faso' and that it is therefore essential to put in place a binding regulatory instrument to help regulate and limit the use of these products.'[3] There are perhaps 1524 kg of mercury in used in thermometers in Burkina Faso at present.

-

India

The project clearly aligns with India's national '*Atmanirbhar Bharat'* policy of self-sustainability. Specifically, the project will help facilitate the growth of a domestic Hg-free manufacturing sector. In addition, the project will strengthen medical and hazardous waste management sectors.

The India MIA is pending. India ratified the Minamata Convention in June 2018.

-

Montenegro

The Montenegro MIA was recently completed with UNDP implementing but has not yet been adopted by the government (GEF 9198). The MIA once adopted, will form an integral part of the Montenegro National Implementation Plan. Preliminary data shared for the purpose of generating the PIF indicate that a net of 5 kg Hg is procured in medical devices each year (4 kg in thermometers; 1 kg in manometers). Montenegro ratified the Minamata Convention in June 2019.

-

Uganda

The Uganda MIA identifies artisanal small-scale gold mining as the primary source of mercury emissions within the country, followed by releases from consumer products. Thermometers alone account for approximately 20 kg/ year in emissions. Perhaps 80 % of liquid filled thermometers in Uganda contain mercury, accounting for more than 20,000 units used in medicine. Significantly, the MIA also estimates the number of sphygmomanometers at above 2,000. Uganda became a Party to the Minamata Convention in March 2019.

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[1] UN Comtrade, 'Download Trade Data | UN Comtrade: International Trade Statistics' <https://comtrade.un.org/data/> accessed 27 June 2020.

[2] Republic of Armenia, 'Minimata Initial Assessment'.

[3] People's Republic of Burkina Faso, 'Minimata Initial Assessment' (2018).

8. Knowledge Management

Outline the Knowledge management approach for the Project, including, if any, plans for the Project to learn from other relevant Projects and initiatives, to assess and document in a user-friendly form, and share these experiences and expertise with relevant stakeholders.

The Knowledge Management Approach for the project will be closely linked to the monitoring and evaluation function and coordinated by the EA. Knowledge management is an important function because of the development of national strategies for phasing out the import, export and manufacture of mercury thermometers and sphygmomanometers in healthcare systems in line with WHO recommendations and related provisions of the Minamata Convention; demonstrations of a phase out in use in at least 3 countries; improving and disseminating knowledge on the phasing-out of mercury-added medical measuring devices, including on their manufacture, import and export; creating an environment conducive to the cessation of procurement and manufacture of mercury-added measuring devices; and providing specific technical expertise on managing mercury-containing medical waste in an environmentally sound manner, from storage to disposal. The project will engage the expertise of the UNEP Global Mercury Partnership, which offers opportunities to learn from ongoing activities as well as for knowledge generation and dissemination.

An explicit aim of the project is to collate, connect, and make available evidence, knowledge, experiences, and good practice examples from countries to stimulate the phase out mercury measuring devices in healthcare. Project results will be made available nationally and shared with other countries participating in this project, and globally, through WHO, UNEP, the UNEP Global Mercury Partnership, and their networks including the International Medical Devices Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world who work to accelerate international medical device regulatory harmonization and convergence.

National and regional workshops, held in project countries, will allow for the sharing of experiences and lessons learned by project countries and other countries in the sub-region that have medical measuring devices as one of their mercury-related priorities.

The Executing Agency will maintain regular communication throughout the project in order to obtain up-to-date information and share results of the project components and ensure smooth and effective implementation of activities. Given the multiple partners involved in the project, UNEP will be cautious of redundancy and keep partners apprised of project progress and developments. As the results of this project are planned to be used for future projects, there will be a strong emphasis on documenting activities and outputs while developing user-friendly communication materials ensuring further dissemination. At the country level, the project will also develop or build on existing country-specific communication and knowledge management plans or platforms to ensure efficient cascading of information down to the healthcare facility level and to ensure sustainability of interventions. These mechanisms will be embedded in existing federal or local government or healthcare facilities, using knowledge products after the end of the project.

With regard to the UNDP-executed GEF ID 10349 project, China has requested that WHO participate in its execution. The activities of 10349 include increasing stakeholders' awareness and knowledge about the phase-out of mercury-added medical devices, and about mercury-free medical facilities, through websites, use of media, and other means. WHO will cooperate with 10349 in sharing and disseminating knowledge about the replacement of mercury thermometers and sphygmomanometers in healthcare through the WHO project website and other means, such as through publications of case studies and newsletters.

WHO will further cooperate with 10349 to ensure incorporation of international best practice and experience in developing national legislation, regulatory frameworks, and capacity-building programs developed to support the phase-out of mercury-added thermometers and sphygmomanometers in healthcare.

As part of cooperation with 10349, WHO will promote the use of new WHO guidance "WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff." These technical specifications include guidance on characteristics, regulatory requirements and standards, calibration, procurement, decontamination, and decommissioning.[1] The guidance responds to concern about the lack of accurate, good-quality devices, especially in low-and middle-income countries through technical consultation and expert review. Under the present project, WHO plans to develop similar guidance for thermometers. WHO also will promote the use of "Decommissioning medical devices," which is new WHO guidance for the process of decommissioning and provide tools for determining why, when, and how to decommission medical devices.[2] It is adaptable to various environments and health systems, especially in low- and middle income countries. The guide also includes disinvestment, a policy decision to withdraw health technology from a health care service when there is evidence that it is clinically ineffective, unsafe, inappropriate or not cost-effective.

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[1] WHO, *WHO Technical Specifications for Automated Non-Invasive Blood Pressure Measuring Devices with Cuff* (2020) <https://apps.who.int/iris/bitstream/handle/10665/331749/9789240002654-eng.pdf?ua=1>.

[2] WHO, *Decommissioning Medical Devices* (2019) <https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf>.

9. Environmental and Social Safeguard (ESS) Risks

Provide information on the identified environmental and social risks and potential impacts associated with the project/program based on your organization's ESS systems and procedures

Overall Project/Program Risk Classification*

PIF	CEO Endorsement/Approval	MTR	TE
Low			

Measures to address identified risks and impacts

Provide preliminary information on the types and levels of risk classifications/ratings of any identified environmental and social risks and potential impacts associated with the project (considering the GEF ESS Minimum Standards) and describe measures to address these risks during the project design.

Text

Text Box: Section 1: Project Overview

Identification	*N/A*
Project Title	*Phasing out mercury measuring devices in healthcare*
Managing Division	
Type/Location	*Global*
Region	*(Africa/ Europe/ North America/ Asia Pacific)*
List Countries	*Albania, Burkina Faso, India, Montenegro Uganda*
Project Description	*The project supports Ministries of Health and Environment in 5 countries to meet their obligations under the Minamata Convention with regard to the manufacture, procurem ent and disposal of Hg-containing medical devices. UNEP GEF Chemicals and Waste Unit will implement with WHO executing. The overall project budget exceeds USD 56 million, including USD 7,980,000 requested in GEF support. The project, which would b e one of only two in this thematic area to receive GEF support, would be executed over a period of 5 years.* *The project is comprised of 4 components. As part of Component 1, national plans wil l be developed for all project countries following existing WHO guidance. Component 2 includes the execution of those plans in 3 of the 5 project countries which will be de cided during the PPG. Components 3 and 4 deal with knowledge management and mo nitoring and evaluation. India is the only country in the project with a substantial Hg-ad ded medical device manufacturing base and will therefore likely be one of the 3 countr ies selected.*

Relevant Subprogrammes	*5*
Estimated duration of project	*60 months*
Estimated cost of the project	*USD 64,260,000*
Name of the UNEP project ma nager responsible	Ludovic Bernaudat
Funding Source(s)	GEF
Executing/Implementing part ner(s)	World Health Organization
SRIF submission version	*If it is not the first time, mark the time of your previous submission* *Concept Review [ ] During Project development [ ] PRC [ ]* *Other __________________*
Safeguard-related reports pre pared so far *(Please attach the documents or provide the hyperlinks)*	· *Feasibility report [ ]* · *Gender Action Plan [ ]* · *Stakeholder Engagement Plan [ ]* · *Safeguard risk assessment or impact assessment [ ]* · *ES Management Plan or Framework [ ]* · *Indigenous Peoples Plan [ ]* · *Cultural Heritage Plan [ ]* · *Others ______________________________*

Text Box: Section 2: Safeguards Risk Summary

A

. **Summary of the Safeguards Risk Triggered**

Safeguard Standards Triggered by the Project	Impact of Risk[1] (1-5)	Probability of Risk (1-5)	Significance of Risk (L, M, H) *Please refer to the matrix below*
SS 1: Biodiversity, Ecosystems and Sustainable Natural Resource Management	1	1	L
SS 2: Climate Change and Disaster Risks	1	1	L
SS 3: Pollution Prevention and Resource Efficiency	2	2	L
SS 4: Community Health, Safety and Security	1	1	L
SS 5: Cultural Heritage	1	1	L
SS 6: Displacement and Involuntary Resettlement	1	1	L
SS 7: Indigenous Peoples	1	1	L
SS 8: Labor and working conditions	1	1	L

B. **ESS Risk Level**[2] **-**

5	H	H	H	H	H
4	M	M	H	H	H
3	L	M	M	M	M
2	L	L	M	M	M
1	L	L	L	L	L
#	1	2	3	4	5

Refer to the UNEP ESSF (Chapter IV) and the UNEP's ESSF Guidelines.

Text Box: Impact

Low risk

Moderate risk

High risk

Additional information required

C. Development of ESS Review Note and Screening Decision

Prepared by

Name: Bret Ericson____________________ Date: _14 Sep 2020________

Screening review by

Name: _____________ Date: __________

Text Box: Signature

Cleared[3]

D. **Safeguard Review Summary** (by the safeguard team)

E. **Safeguard Recommendations** (by the safeguard team)

- No specific safeguard action required

- Take Good Practice approach[4]
- Carry out further assessments (e.g., site visits, experts' inputs, consult affected communities, etc.)
- Carry out impact assessments (by relevant experts) in the risk areas and develop management framework/plan
- Consult Safeguards Advisor early during the full project development phase
- Other ____

Text Box: Section 3: Safeguard Risk Checklist

Screening checklist	Y/N/ Maybe	Justification for the response (please provide answers to each question)
Guiding Principles (these questions should be considered during the project development phase)		
GP1 Has the project analyzed and stated those who are interested and may be affected positively or negatively around the project activities, approaches or results?	Y	Section 2, stakeholders
GP2 Has the project identified and engaged vulnerable, marginalized people, including disabled people, through the informed, inclusive, transparent and equal manner on potential positive or negative implication of the proposed approach and their roles in the project implementation?	N	N/A
GP3 Have local communities or individuals raised human rights or gender equality concerns regarding the project (e.g. during the stakeholder engagement process, grievance processes, public statements)?	N	N/A
GP4 Does the proposed project consider gender-balanced representation in the design and implementation?	Y	Gender action plan will be developed. Gender indicators will be included.
GP5 Did the proposed project analyze relevant gender issues and develop a gender responsive project approach?	N	Gender action plan will be developed. Gender indicators will be included.
GP6 Does the project include a project-specific grievance	N	N/A

redress mechanism? If yes, state the specific location of suc h information.		
GP7 Will or did the project disclose project information, incl uding the safeguard documents? If yes, please list all the web pages where the information is (or will be) disclosed.	N	Will do when available
GP8 Were the stakeholders (including affected communitie s) informed of the projects and grievance redress mechanis m? If yes, describe how they were informed.	N	N/A
GP9 Does the project consider potential negative impacts f rom short-term net gain to the local communities or countrie s at the risk of generating long-term social or economic burd en?[5]	Y	Risks associated with a potential increase i n Hg wastes in the short term are identified in the Risks subsection (5). The project will contribute to reducing these risks
GP10 Does the project consider potential partial economic b enefits while excluding marginalized or vulnerable groups, inc luding women in poverty?	Y	The project envisages economic benefits f or manufacturers of medical devices by re moving the need to maintain two parallel pr oduct lines.
Safeguard Standard 1: Biodiversity, Ecosystems and Sustainable Natural Resource Management		
Would the project potentially involve or lead to:		
1.1 conversion or degradation of habitats (including modi fied habitat, natural habitat and critical natural habitat), or los ses and threats to biodiversity and/or ecosystems and ecosystem services?	N	
1.2 adverse impacts specifically to habitats that are legall y protected, officially proposed for protection, or recognized a s protected by traditional local communities and/or authorita tive sources (e.g. National Park, Nature Conservancy, Indigen ous Community Conserved Area, (ICCA); etc.)?	N	
1.3 conversion or degradation of habitats that are identifie d by authoritative sources for their high conservation and bio diversity value?	N	
1.4 activities that are not legally permitted or are inconsist ent with any officially recognized management plans for the a rea?	N	
1.5 risks to endangered species (e.g. reduction, encroach ment on habitat)?	N	
1.6 activities that may result in soil erosion, deterioration and/or land degradation?	N	
1.7 reduced quality or quantity of ground water or water i	N	

n rivers, ponds, lakes, other wetlands?		
1.8 reforestation, plantation development and/or forest ha rvesting?	N	
1.9 support for agricultural production, animal/fish produc tion and harvesting	N	
1.10 introduction or utilization of any invasive alien species of flora and fauna, whether accidental or intentional?	N	
1.11 handling or utilization of genetically modified organis ms?	N	
1.12 collection and utilization of genetic resources?	N	
Safeguard Standard 2: Climate Change and Disaster Risks		
Would the project potentially involve or lead to:		
2.1 improving resilience against potential climate change impact beyond the project intervention period?	N	
2.2 areas that are now or are projected to be subject to na tural hazards such as extreme temperatures, earthquakes, ex treme precipitation and flooding, landslides, droughts, severe winds, sea level rise, storm surges, tsunami or volcanic erupti ons in the next 30 years?	N	
2.3 outputs and outcomes sensitive or vulnerable to poten tial impacts of climate change (e.g. changes in precipitation, temperature, salinity, extreme events)?	N	
2.4 local communities vulnerable to the impacts of climat e change and disaster risks (e.g. considering level of exposur e and adaptive capacity)?	N	
2.5 increases of greenhouse gas emissions, black carbon emissions or other drivers of climate change?	N	
2.6 Carbon sequestration and reduction of greenhouse e missions, resource-efficient and low carbon development, oth er measures for mitigating climate change	N	
Safeguard Standard 3: Pollution Prevention and Resource Efficiency		
Would the project potentially involve or lead to:		
3.1 the release of pollutants to the environment due to rou tine or non-routine circumstances with the potential for adver se local, regional, and/or transboundary impacts?	Y	The project may increase the amount of Hg -added wastes and plastics wastes resultin g from the proposed transition. These wast es will need to be adequately managed. T he project therefore includes this considera tion under component 2

		tion under component 2.
3.2 the generation of waste (both hazardous and non-hazardous)?	Y	The project may increase the amount of Hg-added wastes and plastics wastes resulting from the proposed transition. These wastes will need to be adequately managed. The project therefore includes this consideration under component 2.
3.3 the manufacture, trade, release, and/or use of hazardous materials and/or chemicals?	N	
3.4 the use of chemicals or materials subject to international bans or phase-outs? (e.g. DDT, PCBs and other chemicals listed in international conventions such as the Montreal Protocol, Minamata Convention, Basel Convention, Rotterdam Convention, Stockholm Convention)	N	
3.5 the application of pesticides or fertilizers that may have a negative effect on the environment (including non-target species) or human health?	N	
3.6 significant consumption of energy, water, or other material inputs?	N	
Safeguard Standard 4: Community Health, Safety and Security		
Would the project potentially involve or lead to:		
4.1 the design, construction, operation and/or decommissioning of structural elements such as new buildings or structures (including those accessed by the public)?	Y	The project could result in new infrastructure to manage wastes, though the development of any infrastructure would not be supported directly by the project.
4.2 air pollution, noise, vibration, traffic, physical hazards, water runoff?	Y	The project may increase the amount of Hg-added wastes and plastics wastes resulting from the proposed transition. These wastes will need to be adequately managed. The project therefore includes this consideration under component 2.
4.3 exposure to water-borne or other vector-borne diseases (e.g. temporary breeding habitats), communicable or noncommunicable diseases?	N	
4.4 adverse impacts on natural resources and/or ecosystem services relevant to the communities' health and safety (e.g. food, surface water purification, natural buffers from flooding)?	N	The project includes a set of activities related hazardous waste management (Hg) under component 2. Hg releases could result though best practices will be encouraged.
4.5 transport, storage use and/or disposal of hazardous o	N	The project includes a set of activities relat

r dangerous materials (e.g. fuel, explosives, other chemicals t hat may cause an emergency event)?		ed hazardous waste management (Hg) under component 2 which will likely include the transport of Hg. Hg releases could result though best practices will be encouraged.
4.6 engagement of security personnel to support project activities (e.g. protection of property or personnel, patrolling of protected areas)?	N	
4.7 an influx of workers to the project area or security personnel (e.g. police, military, other)?	N	
Safeguard Standard 5: Cultural Heritage		
Would the project potentially involve or lead to:		
5.1 activities adjacent to or within a Cultural Heritage site?	N	
5.2 adverse impacts to sites, structures or objects with historical, cultural, artistic, traditional or religious values or to intangible forms of cultural heritage (e.g. knowledge, innovations, practices)?	N	
5.3 utilization of Cultural Heritage for commercial or other purposes (e.g. use of objects, practices, traditional knowledge, tourism)?	N	
5.4 alterations to landscapes and natural features with cultural significance?	N	
5.5 significant land clearing, demolitions, excavations, flooding?	N	
5.6 identification and protection of cultural heritage sites or intangible forms of cultural heritage		
Safeguard Standard 6: Displacement and Involuntary Resettlement		
Would the project potentially involve or lead to:		
6.1 full or partial physical displacement or relocation of people (whether temporary or permanent)?	N	
6.2 economic displacement (e.g. loss of assets or access to assets affecting for example crops, businesses, income generation sources)?	N	
6.2 involuntary restrictions on land/water use that deny a community the use of resources to which they have traditional or recognizable use rights?	N	
6.3 risk of forced evictions?	N	
6.4 changes in land tenure arrangements, including communal and/or customary/traditional land tenure patterns (including temporary/permanent loss of land)?	N	

Safeguard Standard 7: Indigenous Peoples		
Would the project potentially involve or lead to:		
7.1 areas where indigenous peoples are present or uncont acted or isolated indigenous peoples inhabit or where it is bel ieved these peoples may inhabit?	N	
7.2 activities located on lands and territories claimed by i ndigenous peoples?	N	
7.3 impacts to the human rights of indigenous peoples or to the lands, territories and resources claimed by them?	N	
7.4 the utilization and/or commercial development of nat ural resources on lands and territories claimed by indigenous peoples?	N	
7.5 adverse effects on the development priorities, decisio n making mechanisms, and forms of self-government of indi genous peoples as defined by them?	N	
7.6 risks to the traditional livelihoods, physical and cultura l survival of indigenous peoples?	N	
7.7 impacts on the Cultural Heritage of indigenous people s, including through the commercialization or use of their tra ditional knowledge and practices?	N	
Safeguard Standard 8: Labor and working conditions		
8.1 Will the proposed project involve hiring or contracting project staff ?	Y	
If the answer to 8.1 is yes, would the project potentially involv e or lead to:		
8.2 working conditions that do not meet national labour la ws or international commitments (e.g. ILO conventions)?	N	
8.3 the use of forced labor and child labor?	N	
8.4 occupational health and safety risks (including violenc e and harassment)?	Y	The project includes a set of activities relat ed hazardous waste management (Hg) und er component 2. Adequate OSH regimes wi ll need to be put in place to ensure the safe ty of staff related to the project.
8.5 the increase of local or regional unemployment?	N	
8.6 suppliers of goods and services who may have high ri sk of significant safety issues related to their own workers?	N	
8.7 unequal working opportunities and conditions for women	N	

and men		

[1] Refer to UNEP Environmental and Social Sustainability Framework (ESSF): Implementation Guidance Note to assign values to the Impact of Risk and the Probability of Risk to determine the overall significance of Risk (Low, Moderate or High).

[2] **Low risk**: Negative impacts minimal or negligible: no further study or impact management required.
Moderate risk: Potential negative impacts, but limited in scale, not unprecedented or irreversible and generally limited to programme/project area; impacts amenable to management using standard mitigation measures; limited environmental or social analysis may be required to develop a Environmental and Social Management Plan (ESMP). Straightforward application of good practice may be sufficient without additional study.
High risk: Potential for significant negative impacts (e.g. irreversible, unprecedented, cumulative, significant stakeholder concerns); Environmental and Social Impact Assessment (ESIA) (or Strategic Environmental and Social Assessment (SESA)) including a full impact assessment may be required, followed by an effective comprehensive safeguard management plan.

[3] This is signed only for the full projects latest by the PRC time.

[4] Good practice approach: For most low-moderate risk projects, good practice approach may be sufficient. In that case, no separate management plan is necessary. Instead, the project document demonstrates safeguard management approach in the project activities, budget, risks management, stakeholder engagement or/and monitoring segments of the project document to avoid or minimize the identified potential risks without preparing a separate safeguard management plan.

[5] For example, a project may consider investing incommercial shrimp farm by clearing the nearby mangrove forest to improve the livelihood of the coastal community. However, long term economic benefit from the shrip farm may be significantly lower than the mangroves if we consider full costs factoring safety from storms, soil protection, water quality, biodiversity and so on.

Supporting Documents

Upload available ESS supporting documents.

Title	Submitted
Hg_med_devices_SRIF	

Part III: Approval/Endorsement By GEF Operational Focal Point(S) And Gef Agency(ies)

A. RECORD OF ENDORSEMENT OF GEF OPERATIONAL FOCAL POINT (S) ON BEHALF OF THE GOVERNMENT(S): (Please attach the Operational Focal Point endorsement letter with this template).

Name	Position	Ministry	Date
Somanégré Nana	GEF Operational Focal Point	BFA/MINISTRY OF ENVIRONMENT, GREEN ECONOMY AND CLIMATE	9/18/2020
Ivana Vojinović	GEF Operational Focal Point	MNE/MINISTRY OF SUSTAINABLE DEVELOPMENT AND TOURISM	9/24/2020
Patrick Ocailap	GEF Operational Focal Point	UGA/MINISTRY OF FINANCE, PLANNING AND ECONOMIC DEVELOPMENT	9/17/2020
Richa Sharma	GEF Operational Focal Point	IND/MINISTRY OF ENVIRONMENT FOREST AND CLIMATE CHANGE	9/28/2020
Rrezart Fshazi	GEF Operational Focal Point	ALB/Ministry of Tourism and Environment	10/8/2020

ANNEX A: Project Map and Geographic Coordinates

Please provide geo-referenced information and map where the project intervention takes place

Will be defined during PPG