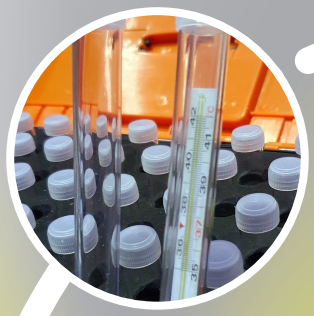
Technical Guidelines for **the Environmentally Sound Management of Mercury-Containing Medical Measuring Devices** in the Philippines

Japan-ASEAN Cooperation



Technical Guidelines for the Environmentally Sound Management of Mercury-Containing Medical Measuring Devices in the Philippines

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Foreword

Now identified as a global problem, mercury pollution poses toxic effects on the environment and human health. A naturally occurring element, Mercury exists in various forms namely elemental mercury, inorganic mercury compounds and methyl mercury, and other organic compounds. It is considered by WHO as one of the top ten chemicals or groups of chemicals of major public health concern.

Mercury is contained in a variety of products, including medical measuring devices such as thermometers and sphygmomanometers. Emissions and releases of mercury in healthcare settings are mainly attributed to damaged equipment and poor waste management practices.

In response to the continued release of mercury into the environment, governments agreed to the Minamata Convention on Mercury. The Minamata Convention on Mercury is an international treaty that aims to protect human health and the environment from the adverse effects of anthropogenic emissions and releases of mercury and mercury compounds. The Philippines was among the 128 countries that signed the Convention during the Conference of Plenipotentiaries on 10 October 2013 in Kumamoto, Japan. The Convention entered into force on 16 August 2017 and was ratified by the country on 08 July 2020. Being a party to the Convention, the Philippines pushes for the phase-out of manufacturing, importing, and exporting mercury-added products.

The Philippines' commitment to the Convention is anchored to the Republic Act (RA) No. 6969 otherwise known as the Toxic Substances and Hazardous and Nuclear Waste Control Act of 1990. This is the national framework for the issuance of DAO 2013-22 (Revised Procedures and Standards on the Management of Hazardous Wastes) and DAO 2019-20 [Revised Chemical Control Order (CCO) for Mercury and Mercury Compounds (Revising DAO 1997-38)]. DAO 2019-20 provides for the regulation on the importation, manufacture, processing, use, and distribution of mercury, mercury compounds, and mercury-added products and their storage while DAO 2013-22 prescribes detailed requirements and procedures for the management of hazardous wastes, including mercury-containing medical measuring devices.

In line with this thrust, the project "Development of Capacity for the Substitution and the Environmentally Sound Management of Mercury-Containing Medical Devices" addresses the development or updating of an inventory of the use, substitution, collection, storage, and disposal of mercury-containing measuring devices. This project is a Japan-ASEAN Integration Fund (JAIF) project endorsed by the ASEAN Working Group on Chemicals and Wastes. It aims to assist the Philippines, an ASEAN Member State, in achieving its obligations as a Party to the Minamata Convention of Mercury, through the promotion of the environmentally sound management of used thermometers and sphygmomanometers in the region.

The two main outputs of the project are the Situation Assessment of Mercury-Containing Medical Measuring Devices in the Philippines and the Technical Guidelines for the Environmentally Sound Management of Mercury-Containing Medical Measuring Devices.

This Technical Guidelines seeks to enhance the capacity of governments, industry, and the general public on the environmentally sound management of mercury-containing medical measuring devices by providing information on international guidelines and best practices, as well as the existing Philippine framework for the management of mercury wastes.

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Introduction

1.1 BACKGROUND

Mercury and mercury compounds are highly toxic substances with adverse effects on humans[1], ecosystems[2], and wildlife[3]. Initially seen as an acute, localized hazard, mercury pollution is now recognized as a global problem, threatening populations and ecosystems distant from the point source of emissions at risk from its toxic effects. As of 2019, it is ranked third in the substance priority list of the US Agency for Toxic Substances and Diseases Registry (ATSDR), just below arsenic and lead, and has been in the list of substances for "virtual elimination" since 1997 (US EPA, 2021).[4]

Mercury is used in a wide variety of products, including medical measuring devices such as thermometers and sphygmomanometers. In particular, emissions and releases in healthcare settings are primarily associated with damaged equipment and poor waste management practices. In a 2005 policy paper, the World Health Organization (WHO) noted that "*of all mercury instruments used in healthcare, the largest amount of mercury is in mercury sphygmomanometers, and their widespread use collectively make them one of the largest mercury reservoirs in the healthcare setting*". Mercury-containing thermometers contain a small bead of mercury (approximately 0.61 to 2.25 grams, depending on the type), whereas mercury-added sphygmomanometers contain substantially more (approximately 64 to 200 grams, depending on the type). While any one piece of mercury-added medical equipment is unlikely to pose a significant human health risk, the aggregate impact of these devices is considerable. A study conducted in Canada in 2004 estimated that more than 2 tons of mercury are release from thermometers alone.[5] Meanwhile, ToxicsLink, a non-government organization (NGO) based in India, found annual national releases of eight tons, 69% of which comes

1 Ye, B., Kim, B., Jeon, M., Kim, S., Kim, H., Jang, T., Chae, H., Choi, W., Na, M. and Hong, Y. (2016). Evaluation of mercury exposure level, clinical diagnosis and treatment for mercury intoxication. *Annals of Occupational and Environmental Medicine,* 28(5).

2 Gworek, B., Dmuchowski, W. and Baczewska-Dabrowska, A.H. (2020). Mercury in the terrestrial environment: A review. *Environmental Sciences Europe,* 32(128).

3 Eagles-Smith, C.A., Silbergerd, E.K., Basu, N., Bustamante, P., Diaz-Barriga, F., Hopkins, W.A., Kidd, K.A. and Nyland, J.F. (2018). Modulators of mercury risk to wildlife and humans in the context of rapid global change. *Ambio,* 47, pp. 170-197.

4 ATSDR. (2020). ATSDR's substance priority list. [online]. Retrieved 25 March 2021 from: https://www.atsdr.cdc.gov/spl/index.html

5 UNEP. (2020). Phasing out mercury measuring devices in healthcare. [online]. Retrieved 25 March 2021 from: https://publicpartnershipdata.azureedge.net/gef/GEFProjectVersions/76dc48eb-dc00-eb11-a813-000d3a337c9e_PIF.pdf

from poorly disposed of mercury-containing sphygmomanometers.[6]

The Minamata Convention on Mercury ("Convention") is a global treaty that aims "*to protect human health and the environment from the anthropogenic emissions and releases of mercury and mercury compounds*" (Minamata Convention, 2013). It was agreed at the fifth session of the Intergovernmental Negotiating Committee (INC) on January 19, 2013, and entered into force on August 16, 2017, 90 days since the date of deposit of the 50th instrument of ratification, acceptance or approval of accession. The Preamble of the Minamata Convention recognizes that mercury is a chemical of global concern owing to its long-range atmospheric transport, its persistence in the environment once released, its ability to bioaccumulate in ecosystems, and its significant negative effects on human health and the environment. As such, it provides a wide range of control over the whole life cycle of mercury—from mercury supply sources and trade, to mercury use in products and processes, to the environmentally sound management (ESM) of its wastes.[7]

The Philippines was among the 128 countries which signed the Convention at a Diplomatic Conference held in Kumamoto, Japan in 2013. On July 8, 2020, the country ratified the Convention, serving as the 123rd country to do so.[8] Before signing the treaty, the Philippines already had in place several regulatory policies against mercury, including Republic Act (RA) No. 6969, or the Toxic Substances and Hazardous and Nuclear Waste Control Act of 1990. The subsequent years saw the development and issuance of several policies regulating mercury, including those covering mercury-containing medical measuring devices (i.e., thermometers and sphygmomanometers) (MCMMDs). In 2008, the Department of Health (DOH) released Administrative Order (AO) No. 21, which called for the gradual phaseout of these devices in the country by 2010. This was supported by policies and regulations released by the Philippine Health Insurance Corporation (Philhealth), the Department of Interior and Local Government (DILG), and the Department of Education (DepEd). In November 2019, the Department of Environment and Natural Resources (DENR) published a revised CCO for mercury and mercury compounds to bring it in line with the provisions of the Convention. Specifically, mercury thermometers and sphygmomanometers are now bound to be phased out by 2022 (DENR AO-2019-20), 12 years after DOH AO 2008-21 and two years after the phase out schedule set by the Convention.

The "Development of Capacity for the Substitution and the Environmentally Sound Management of Mercury-Containing Medical Devices" is a Japan-ASEAN Integration Fund (JAIF) project endorsed by the ASEAN Working Group on Chemicals and Wastes. It aims to assist the Philippines, an ASEAN Member State, in achieving its obligations as a Party to the Minamata Convention, through the promotion of the ESM of used thermometers and sphygmomanometers in the region. Specifically, the project has two main outputs:

1. Inventory of mercury-containing measuring devices (Component 1; Output 1), or the development or update of an inventory on the use, substitution, collection, storage, and disposal of MCMMDs in the Philippines; and

2. Policy gap analysis and guideline development (Component 2; Output 2), or the review of existing guidelines evaluating gaps in their application and the development of recommendations on the ESM of mercury waste from medical measuring devices in the Philippines.

6 ToxicsLink. (2011). Estimation of mercury usage and releases from healthcare instruments in India. [online]. Retrieved 25 March 2021 from: http://toxicslink.org/docs/bmw/MercuryCamp/Estimation_ofmercuryusage_and_releasefrom.pdf

7 Lennett, D. and Guetierrez, R. (2018). Minamata Convention on Mercury ratification and implementation manual. [online]. Retrieved 20 March 2021 from: https://www.nrdc.org/sites/default/files/minamata-convention-on-mercury-manual.pdf

8 Simeon, L.M. (2020). Philippine ratifies treaty on mercury phaseout. [online]. *PhilStar*. Published 13 July. Retrieved 25 March 2021 from: https://www.philstar.com/business/2020/07/13/2027497/philippines-ratifies-treaty-mercury-phaseout#:~:text=MANILA%2C%20Philippines%20%E2%80%94%20The%20Philippines%20has,treaty%20to%20phase%20out%20mercury.&text=The%20Philippines%20is%20among%20the,into%20force%20in%20August%202017

The project was supported by the following organizations:

1. The Asian Institute of Technology (AIT) is an international institute of higher learning. It is Asia's pioneer institution established in 1959 to help meet the region's growing needs for advanced learning in engineering, science, technology and management, research and capacity building. AIT's mission is to develop highly qualified and committed professionals who will play a leading role in the sustainable development of the region and its integration into the global economy. AIT is based in Thailand and has affiliated centers in other parts of the world.

   The project implementing agency—Asian Institute of Technology, Regional Resource Centre for Asia and the Pacific (AIT RRC. AP) is an institute-wide center of AIT that works throughout the region by helping key stakeholders adapt cutting edge science into practical solutions for improved environmental outcomes. Three thematic clusters focusing on reducing air pollution, lessening climate change impacts, and promoting sustainable waste and resource management work to develop the capacity of key stakeholders and contribute to the achievement of international initiatives and frameworks.

2. Project executing partner BAN Toxics is a Philippine-based independent non-government environmental organization that works for the advancement of environmental justice, health, and sustainable development in chemicals and wastes with a special focus on women, children, and other marginalized sectors.

   The organization works closely with government agencies, communities, and civil society at the local, national, and international levels to reduce and eliminate the use of toxic chemicals and support global sustainable development goals through education campaigns, community grassroots interventions, training and capacity-building, policy research and development, and advocacy programs. In its work on mercury, BAN Toxics has been a consistent presence in advocating for the ratification of the Minamata Convention in the Philippines. The organization has also worked closely with various local and international Artisanal and Small-Scale Gold Mining (ASGM) communities to reduce its mercury emissions in countries such as Cambodia, Mongolia, Indonesia, Uganda, and Tanzania.

3. The Department of Environment and Natural Resources (DENR) is the primary agency responsible for the conservation, management, development, and proper use of the Philippines' natural environment and resources, specifically forest and grazing lands, mineral resources, including those in reservation and watershed areas, and lands of the public domain, as well as the licensing and regulation of all natural resources as may be provided by law to ensure equitable sharing of the benefits derived therefrom for the welfare of the present and future generations of Filipinos.

   Specifically, the Environmental Management Bureau (EMB) is the national authority responsible for pollution prevention and control as well as environmental impact assessment. EMB remains the national authority that sets air and water quality standards and monitors ambient and point source pollutants. It manages hazardous and toxic wastes and implements the Philippine Environmental Impact Assessment (EIA) system.

4. The Department of Health (DOH) is the principal health agency in the Philippines. The agency is responsible for ensuring access to basic public health services to all Filipinos through the provision of quality healthcare and the regulation of providers of health goods and services. The DOH aims to contribute towards the development of a productive, resilient, equitable, and people-centered healthcare system.

1.2 OBJECTIVES

The overall objective of the document is to enhance the capacity of governments, industry, and the general public on the ESM of MCMMDs by providing information on international guidelines and best practices, as well as the existing Philippine framework for the management of such wastes. This document consolidates and synthesizes information from a number of technical guidance and policies to answer questions such as: What are mercury wastes? How can mercury wastes be recovered and recycled? Which options and experiences exist for the storage and disposal of mercury wastes?, among others. Through this, target users can make informed choices to promote the ESM of MCMMDs.

1.3 SCOPE OF THE GUIDELINES

1.3.1 Target Users

The main target audience of this document are the technical staff, line officers, and managers of the government agencies involved in the ESM of MCMMDs in the Philippines. The document can also be used by other stakeholders such as MCMMD waste generators and treatment, storage and disposal (TSD) facilities and civil society in the management of mercury wastes.

1.3.2 Outline of the Document

The document delved into the specific guidelines provided by the Minamata and Basel Convention and its associated guidance documents (e.g. ESM Framework, Technical Guidelines). It also enumerated the guidelines identified in several documents prepared by UN agencies, as well as other stakeholders (e.g., civil society, academe, national regulatory agencies, etc.). These guidelines are provided in Chapter III of the document. Meanwhile, the document also explored the specific provisions of the current policy framework in the Philippines, starting with RA 6969 to the National Action Plan for the ESM of mercury-added products (MAPs). These guidelines are provided in Chapter IV of the document. The last chapter of the document highlights the gaps between the two frameworks and informs the Philippine government with additional actions that can be taken to ensure the ESM of MCMMDs.

Overview of Guidelines and Policies for the Environmentally Sound Management of Mercury-Containing Medical Measuring Devices

2.1 MINAMATA CONVENTION ON MERCURY

The Minamata Convention on Mercury is the first multilateral environmental agreement negotiated and ratified in the 21st millennium, addressing the whole life cycle of the element from its mining to its management as waste. It follows and builds on the work of the Basel, Rotterdam, and Stockholm Conventions, by setting out the same basic substantive obligations for all countries, while providing some flexibility and differentiation in some provisions. This approach takes into account the different resources and implementation capabilities of countries, especially the developing nations.

The control provisions of the Convention (Articles 3 to 12) identify the actions that Parties must take to address mercury supply, trade, use, emissions and releases, and manage mercury wastes and mercury-contaminated sites. Article 4 of the Convention is the primary article that outlines the obligations in terms of managing MAPs, defined by the Convention as a "*product or product component that contains mercury or a mercury compound that was intentionally added*" (Article 2 para f). In particular, the Convention prohibits the manufacture, import, or export of any MAP listed in Part I of Annex A of the Convention, which includes MCMMDs. The target phaseout date for this type of product is 2020, which can only be extended if a Party registers for an exemption under Article 6 of the Convention. Note that the use of the listed MAPs already present within the country after the phaseout date is not prohibited, hence, stock mercury thermometers and/or sphygmomanometers in a health facility can still be used after 2020.

MAPs, including MCMMDs become waste when discarded. Article 11 of the Convention includes provisions addressing this type of mercury wastes, which are mutually supportive of the Basel Convention. It defines mercury wastes as substances or objects "*consisting, containing or contaminated*" with mercury or mercury compounds in a quantity above the relevant thresholds that are disposed of, intended to be disposed of, or required to be disposed of by the provisions of national law or the Convention (Article 11 para 2). It further states that each Party shall take appropriate measures to manage mercury waste in an environmentally sound manner, "*taking into account the guidelines developed under the Basel Convention…*" The transport of mercury waste is only allowed for its environmentally sound disposal, in conformity with both the Minamata and Basel Conventions.

In terms of considering the ESM of MAPs and the subsequent waste, the Convention refers to the "best available techniques (BAT)" and "best environmental practices (BEP)". BAT refers to those

techniques that are "*most effective to prevent, and where that is not practicable, to reduce emissions and releases on the environment as a whole, taking into account economic and technical considerations for a given Party or a given facility within the territory of the Party* (Article 2 para b)". BAT are technologies or operational practices that provide the highest level of protection whilst being economically and technically viable in the context of a particular Party, which means that BAT can differ from one Party to another. Meanwhile, BEP refer to the "*application of the most appropriate combination of environmental control measures and strategies* (Article 2 para c)". These definitions reflect the synergistic approach between the Minamata and Basel Conventions, as the former reiterates the need to refer to the latter on the requirements that Parties need to adopt for the ESM of mercury.

The enabling provisions of the Minamata Convention (Articles 13 to 24) are intended to help Parties implement and further develop the Convention, and track progress and measure effectiveness of related management and policy measures. The collective application of these provisions is important to achieve effective treaty implementation among all Parties, and to enhance the ability of different countries and stakeholders to generate scientifically credible information that is both salient to policy development and viewed as politically legitimate. Specifically, the Convention has established several mechanisms to support the achievement of its objectives at the national level, such as Article 13 (Financial resources and mechanisms), Article 14 (Capacity-building, technical assistance and technology transfer), Article 18 (Public information, awareness and education), Article 19 (Research, development and monitoring), and Article 20 (Implementation Plans). It also streamlined mechanisms to support the global achievement of Convention goals, through Article 15 (Implementation and Compliance Committee), Article 17 (Information Exchange), Article 21 (Reporting), and Article 22 (Effectiveness Evaluation).

2.2 BASEL CONVENTION ON THE CONTROL AND TRANSBOUNDARY MOVEMENTS OF HAZARDOUS WASTES AND THEIR DISPOSAL

Increasing environmental awareness and the corresponding tightening of environmental regulations in developed nations in the 1970s had led to rising public resistance to the disposal of hazardous wastes. This led to the onset of the NIMBY (not in my backyard) syndrome, which prompted waste operators to seek cheap disposal options for hazardous wastes in Africa and other parts of the developing world, where environmental awareness and regulations were lacking. The discovery of this "toxic trade" led to the development of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal ("Basel Convention"), which aims to *"protect, by strict control, human health and the environment against the adverse effects resulting from the generation, management, transboundary movements and disposal of hazardous and other wastes"*. Negotiations for the treaty started in the late 1980s, with subsequent adoption by the Conference of Plenipotentiaries in 1989. It entered into force in 1992.

The text of the Basel Convention outlines the general obligations that Parties need to follow to contribute their overarching objectives. Within six months of becoming a Party, countries are required to inform the secretariat (and other Parties) of the wastes, other than those listed in Annex I and II of the Basel Convention, that will be classified as hazardous by national legislation (Article 3 para 1 and 3). Meanwhile, Article 4 para 2 (a-e) and (g) state the key provisions on the ESM, waste minimization, reduction of transboundary movement and disposal practices that Parties need to uphold to mitigate the adverse effects of these wastes on human health and the environment:

The implementation of ESM is an evolutionary process that takes time to achieve, hence, the Framework notes that Parties should develop strategies to foster and enhance its implementation. The development of strategies for ensuring ESM relies on the ability of Parties

"Each Party shall take appropriate measures to:

1. Ensure that the generation of hazardous wastes and other wastes within it is reduced to a minimum, taking into account social, technological and economic aspects;
2. Ensure the availability of adequate disposal facilities, for ESM of hazardous wastes and other wastes, that shall be located, to the extent possible, within it, whatever the place of their disposal;
3. Ensure that persons involved in the management of hazardous wastes or other wastes within it take such steps as are necessary to prevent pollution due to hazardous wastes and other wastes arising from such management and, if such pollution occurs, to minimize the consequences thereof for human health and the environment;
4. Ensure that the transboundary movement of hazardous wastes and other wastes is reduced to the minimum consistent with the environmentally sound and efficient management of such wastes, and is conducted in a manner which will protect human health and the environment against the adverse effects which may result from such movement;
5. Not allow the export of hazardous wastes or other wastes to a State or group of States belonging to an economic and/or political integration organization that are Parties, particularly developing countries, which have prohibited by their legislation all imports, or if it has reason to believe that the wastes in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting; and
6. Prevent the import of hazardous wastes and other wastes if it has reason to believe that the wastes in question will not be managed in an environmentally sound manner.[1]

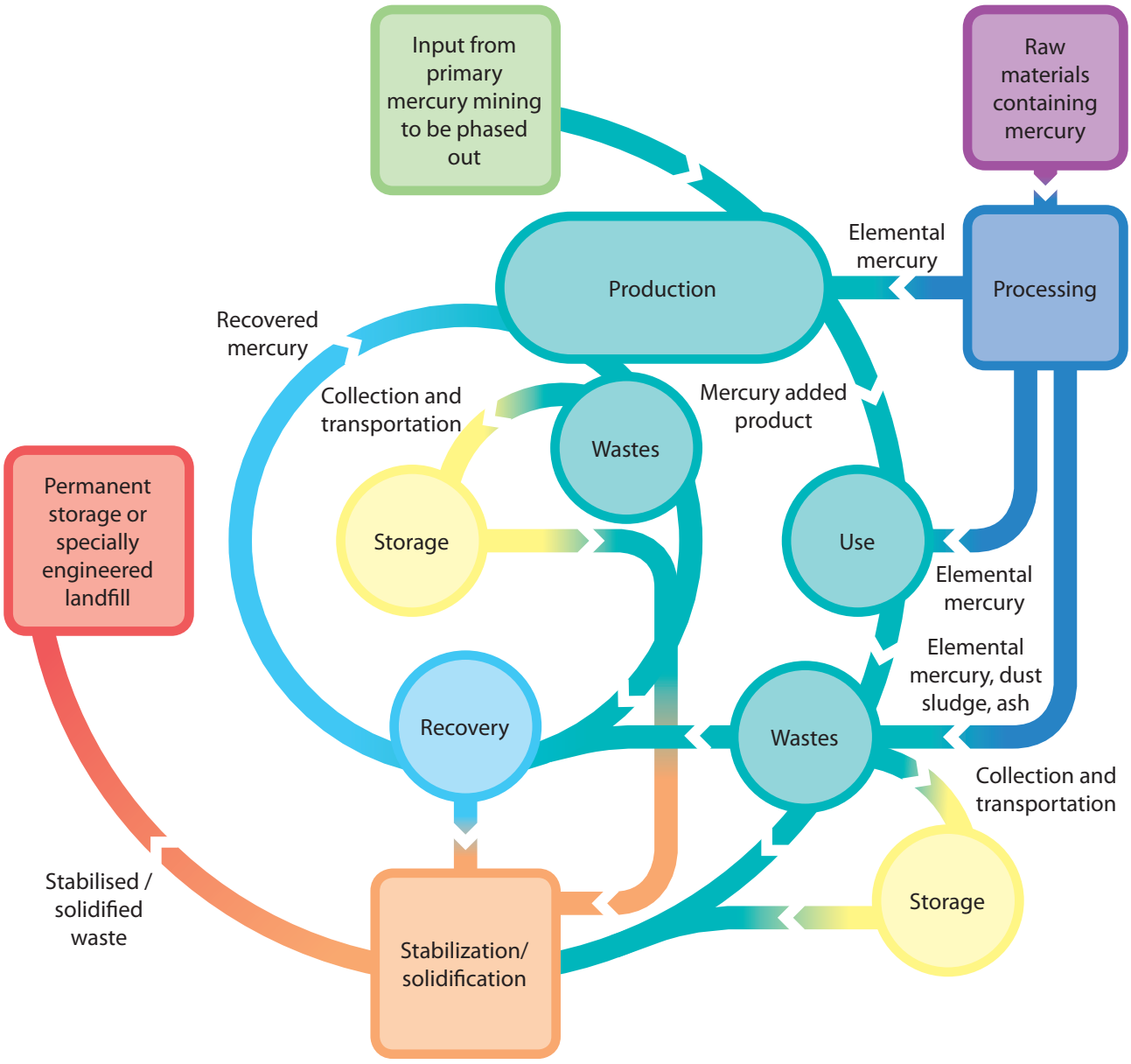
to systematically identify and prioritize issues that need to be addressed. As such, compiling baseline information on a variety of waste-related aspects—from the types of waste stream generated and their quantities, how each should be managed to ensure ESM, and whether there is sufficient capacity to do so, among others—is a crucial first step. With this information, a comprehensive legal framework that effectively governs all waste management operations, protects public and workers' health and safety, and protects the environment can be achieved. Parties to the Basel Convention are required to examine their national controls, standards and procedures to ensure that they agree with their obligations under the Convention. In addition, implementing legislations should also give Governments power to enact and enforce specific rules and regulations, conduct inspections, and establish penalties for violations.

Following the ESM Framework, the COP to the Basel Convention adopted the Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and wastes containing or contaminated with mercury in 2010 and its updated version (the Technical Guidelines on the Environmentally Sound Management of Wastes Consisting of, Containing, or Contaminated with Mercury or Mercury Compounds) ("Technical Guidelines") in 2015. After four years, the COP initiated further updating of the Technical Guidelines by establishing a small intersessional working group (SIWG). The draft updated Technical Guidelines were prepared for the 12th meeting of the OEWG in 2020, and the OEWG agreed to invite Parties and observers to submit comments on the draft. The revised draft updated Technical Guidelines that reflected the comments were prepared for the 15th meeting of the COP, and the COP during the online segment of its 15th meeting from 26 to 30 July 2021 agreed to invite Parties and observers to submit comments on the revised draft by October 15, 2021.

The purpose of the Technical Guidelines is to *"provide guidance on the ESM of mercury wastes*

9 Basel Convention. (2011). Text of the Basel Convention. [online]. Retrieved 21 May 2021 from: http://www.basel.int/TheConvention/Overview/TextoftheConvention/tabid/1275/Default.aspx

Figure 1 **Life Cycle Management of Mercury as recommended by the Basel Convention Technical Guidelines[10]**



pursuant to decisions under the Basel and the Minamata Conventions". The Technical Guidelines address specific provisions of the Minamata Convention relating to definitions and appropriate measures and methods to dispose of mercury waste in an environmentally sound manner (i.e., Article 11 of the Convention). MCMMDs are included in the B1 category of wastes covered by the Technical Guidelines (i.e., B1: wastes of mercury-added products that easily release mercury into the environment, including when they are broken (e.g., mercury thermometers, fluorescent lamps)). While Article 11 para 2 of the Minamata Convention mentions a "threshold" for the disposal of mercury waste, the COP to the Minamata Convention decided at its 3rd meeting (MC-3/5) in 2019 that no threshold needs to be established for "*mercury wastes falling under Article 11 para 2(b)*", which means that MAPs

10 UNEP. (2020). Draft updated technical guidelines on the environmentally sound management of wastes consisting of, containing or contaminated with mercury or mercury compounds. [online]. Retrieved 27 May 2021 from: http://www.basel.int/Implementation/MercuryWastes/TechnicalGuidelines/tabid/5159/Default.aspx

which are disposed of or are intended to be disposed of, or are required to be disposed of by the provisions of national law or the Minamata Convention are regarded as such waste. According to the non-exhaustive list of waste containing mercury or mercury compounds in the decision MC-3/5, sources of MCMMDs to be considered as mercury waste include hospitals, clinics, healthcare facilities (both human and animal), pharmacies, households, schools, laboratories, and universities, among others.

The Technical Guidelines of the Basel Convention employ the life cycle approach to promote the ESM of mercury wastes (Figure 1). In the life cycle management of mercury, the reduction of mercury use in products and processes is prioritized, thereby reducing the mercury content of wastes resulting from these products and processes. When using MAPs, special care should be taken to avoid emissions or releases of mercury into the environment. Wastes containing mercury should be treated to immobilize mercury in an environmentally sound manner. In cases where mercury is recovered, it should be disposed of, after stabilization and/or solidification (S/S), at a permanent storage site or a specially engineered landfill (SEL). Alternatively, the recovered mercury can be used as an input in products or processes still allowed under the Minamata Convention. Mercury wastes maybe stored pending further treatment or disposal, or until export to other countries where ESM is possible.

11 UNDP. (2010). Guidance on the cleanup, temporary or intermediate storage and transport of mercury waste from healthcare facilities. [online]. Retrieved 1 July 2021 from: https://noharm-global.org/documents/guidance-cleanup-temporary-or-intermediate-storage-and-transport-mercury-waste-healthcare

12 UNEP. (2000). Methodological guide for the undertaking of national inventories of hazardous wastes within the framework of the Basel Convention. [online]. Retrieved 1 July 2021 from: http://www.basel.int/Portals/4/Basel%20Convention/docs/pub/metologicalguidee.pdf

13 UNEP. (2013). Mercury: Acting Now!. [online]. Retrieved 1 July 2021 from: https://web.unep.org/globalmercurypartnership/mercury-acting-now

14 UNEP and ISWA. (2015). Practical sourcebook on mercury waste storage and disposal. [online]. Retrieved 1 July 2021 from: https://www.unep.org/resources/report/practical-sourcebook-mercury-waste-storage-and-disposal-2015

Table 1 **Guidance documents developed by UN Agencies**

UN Agency	Title	Description
UNEP	Guidance on the cleanup, temporary or intermediate storage and transport of mercury waste from healthcare facilities[11]	The objective of the document is to provide guidance to health facilities on the cleanup and temporary on-site storage of mercury, the transport of mercury waste, and its intermediate storage at a centralized facility
	Methodological guide for the undertaking of national inventories of hazardous wastes within the framework of the Basel Convention[12]	The guide aims to provide simple and practical instructions to competent authorities in conducting inventories of hazardous wastes
	Mercury: Acting Now! [13] (developed under the Global Mercury Partnership, GMP)	The UNEP GMP was initiated in 2005 as a voluntary, multi-stakeholder partnership working on eight work areas (such as mercury reduction in products). The document specifically consolidates the work (e.g. pilot projects) of the GMP in line with the Basel and Minamata Convention.
	Practical sourcebook on mercury waste storage and disposal[14] developed with the International Solid Waste Association (ISWA))	The sourcebook aims to provide information on commercially available storage and disposal technologies for mercury wastes.

UN Agency	Title	Description
	Manual for the implementation of the Basel Convention[15]	The manual is designed to assist Parties and potential Parties to understand the obligations set out in the Basel Convention and how to implement them.
	Guidance on BAT and BEP[16]	This document sets out guidance on controlling emissions of mercury and mercury compounds to air from point sources
	Guidelines on the environmentally sound interim storage of mercury, other than waste mercury[17]	These guidelines provide guidance for the environmentally sound interim storage of mercury and mercury compounds intended for a use allowed to a Party under the Convention
	Guide for the development of national legal frameworks to implement the Basel Convention[18]	This document serves as a reference to any Party or potential Party facing difficulties in drafting implementing legislation.
	Toolkit for identification and quantification of mercury releases[19]	The Toolkit intends to assist countries in identifying and quantifying the sources of mercury releases by developing a comprehensive national mercury releases inventory.
UNIDO	No time to waste: International expert group meeting on the sustainable management of mercury waste[20]	This document consolidates the result of the international expert group meeting on the management of mercury waste, from interim storage, treatment to final disposal.
WHO	Replacement of mercury thermometers and sphygmomanometers in healthcare: Technical Guidance[21]	This guide is designed to provide step-by-step instructions for the safe substitution of mercury-free thermometers and sphygmomanometers in healthcare settings.
	Procurement process guide[22]	This document is a planning aid and checklist for procurement process development and assessment.
	Safe management of wastes from healthcare activities[23]	Also called the "Blue Book", this document outlines the steps for the safe, sustainable and affordable management of healthcare waste.

15 UNEP. (2016). Manual for the implementation of the Basel Convention. [online]. Retrieved 1 May 2021 from: http://www.basel.int/Implementation/Publications/GuidanceManuals

16 UNEP. (2017). Guidance on BAT and BEP. [online]. Retrieved 1 May 2021 from: https://www.mercuryconvention.org/Portals/11/documents/forms-guidance/English/BATBEP_introduction.pdf

17 UNEP. (2018). Guidelines on the environmentally sound interim storage of mercury, other than waste mercury. [online]. Retrieved 1 May 2021 from: http://www.mercuryconvention.org/Portals/11/documents/meetings/COP1/intersessional/storage%20guidelines%201704.docx

18 UNEP. (2019a). Guide for the development of national legal frameworks to implement the Basel Convention. [online]. Retrieved 1 April 2021 from: http://www.basel.int/Implementation/Publications/GuidanceManuals

19 UNEP. (2019b). Toolkit for identification and quantification of mercury releases. [online]. Retrieved 15 April 2021 from: https://www.unep.org/explore-topics/chemicals-waste/what-we-do/mercury/mercury-inventory-toolkit

20 UNEP. (2021). Catalogue of technologies and services on mercury waste management. [online]. Retrieved 1 June 2021 from: https://web.unep.org/globalmercurypartnership/catalogue-technologies-and-services-mercury-waste-management-2021-version

21 UNIDO. (2018). No time to waste: International expert group meeting on the sustainable management of mercury waste. [online]. Retrieved 1 June 2021 from: https://www.unido.org/sites/default/files/files/2019-02/MWaste%20Booklet.pdf

22 WHO. (2011a). Replacement of mercury thermometers and sphygmomanometers in healthcare: Technical Guidance. [online]. Retrieved 30 April 2021 from: https://apps.who.int/iris/handle/10665/44592

23 WHO. (2011b). Procurement process guide. [online]. Retrieved 27 March 2021 from: https://www.who.int/publications/i/item/9789241501378

UN Agency	Title	Description
	Developing national strategies for phasing out mercury-containing thermometers and sphygmomanometers in healthcare, including in the context of the Minamata Convention on Mercury[24]	The publication aims to guide health departments/ ministries in planning and leading the development of national strategies to phase out MCMMDs in health care, including through substitution and replacement with alternatives. Sample activities and objectives were highlighted, including the issues that may require more in depth consideration depending on the context of the country.
	Developing national strategies for phasing out mercury-containing thermometers and sphygmomanometers in healthcare, including in the context of the Minamata Convention on Mercury[25]	The publication aims to guide health departments/ ministries in planning and leading the development of national strategies to phase out MCMMDs in health care, including through substitution and replacement with alternatives. Sample activities and objectives were highlighted, including the issues that may require more in depth consideration depending on the context of the country.
	Global model regulatory framework for medical devices, including in vitro devices (IVDs)[26]	The document aims to guide and support WHO Member States in developing and implementing regulatory controls relating to medical devices to ensure the quality and safety of the devices available within their jurisdictions.
	Strategic planning for implementation of the health-related articles of the Minamata Convention[27]	The publication aims to guide health departments/ ministries in planning measures to implement the health-related articles (both obligatory and not obligatory) of the Minamata Convention.
	Decommissioning medical devices[28]	This document is part of a series of technical documents which guides the process of decommissioning and provide tools for determining why, when, and how to decommission medical devices.
	Technical specifications for automated non-invasive blood pressure measuring devices (BPMDs) with cuff[29]	This document describes the performance and technical aspects of automated non-invasive BPMDs, thereby providing guidance to procurement agencies and regulatory authorities to prepare policy, management and supply accordingly.
	Technical specifications for complementary medical equipment to support COVID-19 management[30]	While created in relation to the COVID-19 pandemic, this technical document describes the latest performance and technical aspects of infrared and digital thermometers.

24 WHO. (2014). Safe management of wastes from healthcare activities. [online]. Retrieved 27 March 2021 from: https://www.euro.who.int/__data/assets/pdf_file/0012/268779/Safe-management-of-wastes-from-health-care-activities-Eng.pdf

25 WHO. (2015). Developing national strategies for phasing out mercury-containing thermometers and sphygmomanometers in healthcare, including in the context of the Minamata Convention on Mercury. [online]. Retrieved 27 March 2021 from: https://apps.who.int/iris/handle/10665/259448

26 WHO. (2016). Global model regulatory framework for medical devices, including in vitro devices (IVDs). [online]. Retrieved 27 March 2021 from: https://apps.who.int/iris/handle/10665/255177

27 WHO. (2019a). Strategic planning for the implementation of health-related articles of the Minamata Convention on Mercury. [online]. Retrieved 25 March 2021 from: https://www.who.int/publications-detail-redirect/9789241516846

28 WHO. (2019b). Decommissioning medical devices. [online]. Retrieved 25 March 2021 from: https://apps.who.int/iris/handle/10665/330095

29 WHO. (2020a). Technical specifications for automated non-invasive blood pressure measuring devices (BPMDs) with cuff. [online]. Retrieved 27 March 2021 from: https://www.who.int/docs/default-source/searo/indonesia/who-tech-spec-for-automated-non-invasive-blood-pressure-measuring-devices-with-cuff.pdf?sfvrsn=b112be47_2

30 WHO. (2020b). Technical specifications for complementary medical equipment to support COVID-19 management. [online]. Retrieved 27 March 2021 from: https://www.jstor.org/stable/resrep27993.10?seq=1#metadata_info_tab_contents

Table 2 **Guidance documents developed by other stakeholders**

Organization	Title	Description
BAN Toxics	Policy paper on the ESM of mercury and mercury compounds in the Philippines[31]	This document examined the policy options for the environmentally sound disposal of mercury and mercury compounds, and consolidated criteria for selecting disposal options.
European Environmental Bureau (EEB) and Zero Mercury Working Group	Guide and checklist for phasing out mercury-added products under the Minamata Convention on Mercury[32]	This document provides a simplified list of steps governments may take in preparing to undertake the obligations under Article 4 of the Minamata Convention.
Healthcare without Harm (HCWH)	The global movement for mercury-free healthcare[33]	The document provides case studies/ examples of initiatives to eliminate mercury in the healthcare in both developed and developing country contexts.
	Guide for eliminating mercury from healthcare establishments[34]	The document outlines the five steps for eliminating mercury in the healthcare setting
University of Massachusetts Lowell	An investigation of alternatives to mercury-containing products[35]	This study provides an in depth investigation of existing alternatives to MCMMDs
	Eliminating mercury in healthcare: A workbook to identify safer alternatives[36]	This workbook provides guidance for a systematic, hospital-wide approach for education, assessment and improvement of mercury-containing products and practices related to mercury.
Organization for Economic Cooperation and Development (OECD)	Guidance manual for the implementation of the OECD recommendation C(2004)100 on ESM of waste[37]	This publication aims to facilitate the implementation of ESM policy by governments and waste treatment facilities, in line with the OECD recommendation C(2004)100.
US EPA	Eliminating mercury in hospitals: Environmental best practices for health care facilities[38]	The document outlines the key steps in eliminating mercury in the healthcare settings, including comparisons between mercury and mercury-free medical devices.

31 BAN Toxics. (2014). Policy paper on the ESM of mercury and mercury compounds in the Philippines. Quezon City, Philippines.

32 EEB and ZMWG. (2014). Guide and checklist for phasing out mercury-added products under the Minamata Convention on Mercury. [online]. Retrieved 25 March 2021 from: https://web.unep.org/globalmercurypartnership/guide-and-checklist-phasing-out-mercury-added-products-under-minamata-convention-mercury

33 HCWH. (2007). The global movement for mercury-free healthcare. [online]. Retrieved 20 March 2021 from: https://noharm-global.org/sites/default/files/documents-files/746/Global_Mvmt_Mercury-Free.pdf

34 HCWH. (2017). Guide for eliminating mercury from healthcare establishments. [online]. Retrieved 20 March 2021 from: https://noharm-global.org/sites/default/files/documents-files/2460/Mercury_Elimination_Guide_for_Hospitals.pdf

35 University of Massachusetts Lowell. (2003). An investigation of alternatives to mercury-containing products. [online]. Retrieved 1 April from: https://web.unep.org/globalmercurypartnership/investigation-alternatives-mercury-containing-products

36 University of Massachusetts Lowell. (2012). Eliminating mercury in healthcare: A workbook to identify safer alternatives. [online]. Retrieved 1 April from: https://www.uml.edu/docs/EliminatingMercuryInHealthCare_English_tcm18-187545.pdf

37 OECD. (2007). Guidance manual for the implementation of the OECD recommendation C(2004)100 on ESM of waste. [online]. Retrieved 20 March 2021 from: https://legalinstruments.oecd.org/public/doc/51/51.en.pdf

38 US EPA. (2002). Eliminating mercury in hospitals: Environmental best practices for health care facilities. [online]. Retrieved 1 April from: https://19january2017snapshot.epa.gov/www3/region9/waste/archive/p2/projects/hospital/mercury.pdf

2.3 INTERNATIONAL GUIDANCE DOCUMENTS AND BEST PRACTICES

The development and adoption of the Minamata and Basel Conventions, along with other multilateral environmental agreements (MEAs) such as the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade ("Rotterdam Convention") and the Stockholm Convention on Persistent Organic Pollutants ("Stockholm Convention"), is coupled with the development of several guidance documents by relevant United Nations (UN) agencies. These UN agencies, which include UNEP, UNIDO, UNDP, and WHO, provide technical assistance to Parties by spelling out the key steps and guidelines that can be taken to implement the requirements and provisions of the MEAs at the subnational, national, regional and global levels. This includes the development of guidance documents that compile BAT/ BEP and/or policy actions needed to manage the specific chemical or waste (Table 1), which can be referred to in conjunction with this document.

In parallel to the guidance documents developed by UN agencies, other stakeholders (e.g., civil society organizations, national government authorities, academe, etc.) have developed their own documents aimed at consolidating best practices in implementing the provisions of the aforementioned MEAs (Table 2). These documents can be referred to in conjunction with this report.

2.4 PHILIPPINE LAWS AND POLICIES REGULATING MERCURY AND MERCURY WASTES

The main foundation of the country's environmental policy framework is the Constitution. Article 2 sections 15 and 16 state that the Philippine government has a mandate to protect the rights of Filipinos to health and to a balanced and healthy environment. This has resulted to the enactment of national legislations protecting human health and the environment from the negative impacts of chemicals and wastes, which were further supported by the issuance of department orders and other policies that operationalize the provisions of national laws (Table 3).

2.4.1 Republic Act 6969 - An Act to Control Toxic Substances and Hazardous and Nuclear Wastes, Providing Penalties for Violations Thereof and for Other Purposes

Also known as the "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990", the law mandates the control and regulation of the import, manufacture, processing, handling, storage, transport, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk and/or injury to health or the environment, as well as the storage, treatment, and disposal of hazardous and nuclear wastes in the country. It also defines the general requirements on pre-manufacture and pre-importation of chemicals (section 8), testing (section 9) and exemptions (section 11) and outlines the prohibited acts (section 13) and their corresponding penalties and fines (sections 14 and 15). Provisions requiring public access to records, reports and notifications are also in place (section 12), requiring the DENR to release pertinent information without violating confidentiality clauses.

More so, RA 6969 led to the establishment of an inter-agency advisory council which will assist the DENR in formulating pertinent rules and regulations for the effective implementation of the law. The council is led by the Secretary of the DENR and composed of the secretaries from the DOH, Department of Trade and Industry (DTI), Department of Science and Technology (DOST), Department of National Defense (DND), Department of Foreign Affairs (DFA), Department of Labor and Employment (DOLE), Department of Finance (DOF), Department of Agriculture (DA) and a representative from a non-government organization.

To implement the provisions of RA 6969, DENR released DAO 1992-29, or the "Implementing Rules and Regulations (IRR) of RA 6969", which further articulated (1) the powers and functions of the DENR; (2) the scope and extent of the inventory of chemical substances; (3) the creation of a Priority Chemical List (PCL); and (4) the requirements

Table 3 **Philippine Policy Framework for Mercury and Mercury Wastes**

Legislation	IRR
RA 6969, Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990	DAO 1992-29 (IRR) DAO 2019-20 (CCO on mercury) DAO 2013-22 (Revised Procedures for the Management of Hazardous Wastes)
RA 9003, Ecological Solid Waste Management Act of 2000	DAO 2001-34
RA 8749, Philippine Clean Air Act of 1999	DAO 2000-81
RA 9275, Philippine Clean Water Act of 2004	DAO 2005-10
Presidential Decree 1586, Environmental Impact System of 1978	DAO 2003-30
RA 9711, Food and Drug Act of 2009	Draft circular for the phaseout of MCMMDs
DOH AO 2008-21	Related policies: ▪ DILG MC 2010-140 ▪ DepEd MC 2010-160 ▪ Philhealth benchbook ▪ DOH DM 2017-0302 ▪ DOH Healthcare waste management manual
JAO 2005-02, Policies and Guidelines on the Effective and Proper Handling, Collection, Transport, Treatment, Storage and Disposal of Healthcare Wastes	--
NAP for the Phaseout of MAPs and the Management of the Associated Mercury-Containing Wastes	--

	Scope	Regulation of Mercury/ MCMMDs
	Mandates the control and regulation of the import, manufacture, processing, handling, storage, transport, sale, distribution, use and disposal of chemical substances and mixtures that present unreasonable risk and/or injury to health or the environment, as well as the storage, treatment, and disposal of hazardous and nuclear wastes in the country.	Lists mercury as a priority chemical; regulates mercury, mercury compounds and MAPs through a CCO; requires the proper management (generators, transporters, TSD facilities) of mercury
	Provides a systematic, comprehensive and ecological solid waste management program through the development and implementation of subnational and national solid waste management plans and the establishment of a National Solid Waste Management Commission and Solid Waste Management Boards at the provincial and city/ municipal levels.	While RA 9003 focuses mostly on municipal wastes, it also recognizes the need to manage "special wastes", which are comprised of household hazardous wastes. The law requires that plans include information on the proper handling and disposal practices for special wastes, and designates the responsibility of collection and disposal of this type of wastes to the local government unit (LGU).
	Controls the release of toxic and hazardous pollutants in the atmosphere by providing air quality standards for criteria pollutants. The IRR contains specific provisions for the National Ambient Air Quality Guideline Values and National Emission Standards.	The law covers mercury emissions from stationary sources and no-burn technologies, which can cover TSD facilities managing mercury wastes. The maximum permissible limit of 5 mg Hg/ Ncm.
	Ensures water quality management in all water bodies by controlling the release of toxic and hazardous pollutants. This involves the creation of a water quality management system that includes (1) the identification of water quality management areas; (2) a national sewerage and septage management program; and (3) domestic collection, treatment and disposal systems. Specifically, the IRR enumerates the requirements for the disposal of effluents, sewage and septage offsite and the disposal of industrial water on land and offshore.	Mercury is part of the secondary parameters that need to be monitored as part of EIAs of TSD facilities. Depending on the classification of the impacted water body, values range from 0.001-0.004 mg Hg/L.
	The law includes regulatory requirements for the conduct of an EIA, as well as the recognition of projects and areas that can be considered as environmentally critical and would require an EIA	Hospitals, healthcare facilities and TSD facilities are required to apply for an ECC prior to operation.
	RA 9711 paved the way for the establishment of the CDRRHR, which regulates the manufacture, import, export, distribution, promotion, advertisement, and sale of medical devices, radiation devices and health-related devices	Thermometers are included in the list of medical devices requiring registration (i.e., requiring CPR). Also, the impending the draft circular aims to ban the manufacture, distribution, importation/ export, sale/ offer for sale (including through digital platforms), donation, transfer, use, and promotion/ advertising/ sponsorship of MCMMDs
	Requires all hospitals to follow the guidelines for the gradual phase-out of mercury in health care facilities	This is the main legislation which phase out MCMMDs in the healthcare setting
	The JAO provides guidelines for the management of biological and hazardous wastes generated from health care facilities and clarifies the jurisdiction, authority, and responsibilities between DENR and DOH	The JAO reiterates the provisions of other policies (e.g. DAO 2013-22, DOH AO 2008-21, etc.)
	Detail the 5-year implementation plan for the ESM of mercury-containing products in accordance with the provisions of the Minamata and Basel Conventions	Specific activities for MCMMDs are provided in Table 19.

Table 4 **Scope of DENR AO 1992-29**

Requirements	Scope	Regulation of Mercury
Establishment of the Philippine Inventory of Chemicals and Chemical Substances (PICCS)	The PICCS is a list of all existing chemicals and chemical substances used, imported, distributed, processed, manufactured, stored, exported, treated or transported in the country. A pre-manufacturing and pre-importation notification (PMPIN) is needed if a new chemical needs to be included in the PICCS. Manufacturers and importers will not need a notification and clearance from the Environmental Management Bureau (EMB) for chemicals included in the PICCS as long as they are not covered in the PCL and any CCO.	Mercury (elemental) is included in the PICCS, along with mercury compounds such as: ▪ mercury bromide ▪ mercury (II) nitrate ▪ phenylmercury (II) hydroxide ▪ mercury (II) chloride ▪ mercury (II) ammonium chloride ▪ mercury amide chloride ▪ mercury (I) nitrate ▪ mercury (II) phosphate ▪ mercury (II) oxycyanide ▪ mercury (II) sulfide ▪ mercury sulfide ▪ mercury bisulfite ▪ mercury sulfate ▪ etc.
Priority Chemical List (PCL)	The PCL is a list of existing and new chemicals that the DENR EMB has determined to potentially pose unreasonable risk to human health and the environment.	Mercury compounds are included in the PCL.
Chemical Control Order (CCO)	A CCO prohibits, limits, or regulates the use, manufacture, import, transport, processing, storage, possession, and wholesale of priority chemicals determined by the DENR EMB.	A CCO on mercury and mercury compounds was first issued in 1997, with DAO 1997-38, and was subsequently amended by DAO 2019-20. Details of this CCO will be discussed in a separate section.

for the issuance of a CCO (Table 4). The IRR also contained specific provisions on hazardous wastes, although this has been amended by DAO 2004-36, then DAO 2013-22. The latter will be covered in another section of the document.

2.4.1.1 DAO 2019-20 – CCO for Mercury and Mercury Compounds

The first CCO on mercury and mercury compounds was issued in 1997 (DAO-1997-38), which was then updated in 2019 with DAO 2019-20. The CCO applies to the importation, manufacture, processing, use and distribution of mercury, mercury compounds and MAPs; and addresses the treatment, storage and disposal of mercury-bearing or mercury-contaminated wastes in the Philippines. Specifically, the CCO has set 2022 as the phaseout schedule for MCMMDs, thereby prohibiting their importation, manufacture, use, distribution and storage. This means that MCMMDs will be considered as waste and will require proper treatment and disposal in an environmentally sound manner.

The CCO provides specific requirements for any person or entity involved in importing, manufacturing, distributing, and using mercury, mercury compounds or MAPs. Required permits for medical devices need to be obtained from the Center for Device Regulation, Radiation, Health and Research (CDRRHR) Office of the Food and Drug Administration (FDA) and importation clearance from the DENR-EMB. The registration and importation clearance will require, among others, information on the importing party (e.g. permit to operate, discharge permit, ECC, etc.), as well as their mercury management plan, contingency plan and notarized certificate of liabilities to compensate damages.

Other pertinent requirements of the CCO include those covering handling and labeling, storage, plans for spill prevention and cleanup as well as facility closure, IEC and training, and insurance and safety bond. Specific information on these requirements are discussed in another section of the report. All entities covered by the CCO are required to keep a record of all transactions relevant to the CCO, which can also be used for the development of quarterly and annual reports that will be submitted to DENR EMB. These reports will be made available for public access, except for information that are covered by confidentiality clauses set by DAO 1992-29.

2.4.1.2 DAO 2013-22 – Revised Procedures and Standards for the Management of Hazardous Wastes

An amended version of DAO 2004-36, DAO 2013-22 has two main objectives:

1. Ensure that the requirements for hazardous waste generators, transporters and treaters are developed and presented in a useful information/ reference document for various stakeholders; and

2. Further streamline the procedures for generation and compliance to the legal and technical requirements for hazardous waste management.

Mercury and mercury compounds are classified as hazardous waste (waster number D407), which includes all wastes with concentration > 0.1 mg/L based on analysis of an extract. This includes all MCMMDs that have been phased out due to the CCO (as well as other policies such as DOH AO 2008-21). With this, the DAO contains information on requirements covering the following aspects, which will be further discussed in detail in a separate section of the report:

- Waste generators, waste transporters, and treatment, storage and disposal (TSD) facilities;
- Storage and labeling;
- Waste transport record;
- Contingency program and planning;
- Personnel training;
- Import of recyclable materials containing hazardous substances and export of hazardous wastes;
- Monitoring and schedule of fees; and
- Prohibited acts and penalties.

2.4.2 RA 9003 – An Act Providing for An Ecological Solid Waste Management Program, Creating the Necessary Institutional Mechanisms and Incentives, Declaring Certain Acts Prohibited and Providing Penalties, Appropriating Therefor, and for Other Purposes

The Ecological Solid Waste Management Act of 2000 aims to establish a systematic, comprehensive, and ecological solid waste management program in the country, which involves the following:

- Promotion of the environmentally sound utilization of resources and resource conservation and recovery;
- Establishment of guidelines, targets and measures for solid waste avoidance and reduction;
- Implementation of the proper segregation, collection, transport, storage, treatment and disposal of solid waste through BAT and BEP;
- Promotion of research and development to enhance solid waste management programs and techniques;
- Recognition of the leading role of local government units (LGUs) in waste management, supported by the national government and other stakeholders such as the private sector;
- Institutionalization of public participation in the development and implementation of plans and activities; and

- Strengthening of ecological solid waste management through integration in both formal and non-formal education

RA 9003 led to the creation of the National Solid Waste Management Commission (NSWMC) and outlined the functions of the office and the roles and responsibilities of its members. It is composed of representatives from national government agencies and local government organizations, NGOs, the recycling and manufacturing/ packaging industry. In addition, the law led to the creation of Solid Waste Management Boards at the provincial and city/ municipal levels, which are responsible for the preparation and implementation of plans for the management of solid wastes under their geographic area/ political coverage. The NSWMC will oversee the implementation of these plans and prescribe policies to achieve the objectives of the RA.

DAO 2001-34 serves as the IRR of the law, and contains specific guidelines for the creation and implementation of a comprehensive solid waste management system, waste segregation, collection, transport and handling of solid wastes, materials recovery facilities and composting, recycling program operations of controlled dumpsites and sanitary landfills, and financing of solid waste management initiatives. While RA 9003 focuses mostly on municipal wastes, it also recognizes the need to manage "special wastes", which are comprised of household hazardous wastes. The law requires that plans include information on the proper handling and disposal practices for special wastes and assigns the responsibility of collection and disposal of this type of wastes to the local government unit (LGU).

2.4.3 RA 8749 – An Act Providing for a Comprehensive Air Pollution Control Policy and for Other Purposes

RA 8749, also known as the Philippine Clean Air Act of 1999, highlights the responsibility of the State to protect and advance the right of Filipinos to a balance and healthy ecology. The law aims to formulate a holistic national program for air pollution management, founded on the "polluters pay principle". It also promotes:

1. Cooperation and self-regulation among citizens and industries through the application of market-based instruments;

2. Primacy of pollution prevention measures over pollution control;

3. The need for public information and education, as well as the participation of the public in air quality planning and monitoring; and

4. Accountability for environmental impacts caused by any activity, through the establishment of an environmental guarantee fund or mechanism.

To achieve these, the law created an air quality management system composed of the following:

- Integrated Air Quality Improvement Framework, which prescribes the emission reduction goals using permissible standards, control strategies and control measures to undertaken within a specified time period, including cost-effective use of economic incentives, management strategies, collective actions, and environmental education and information

- Air Quality Monitoring and Information Network, which will enable the development of an annual National Air Quality Status report;

- Air Quality Control Action Plan, which is based on the Integrated Air Quality Control Framework and includes BAT and BEP for air quality;

- Air Quality Guideline Values and Standards, or a list of hazardous air pollutants with corresponding ambient guideline values and/ or standard necessary to protect health and safety, and general welfare;

- Emission Charge System for mobile sources of pollution;

- Air Quality Management Fund, which will finance containment, removal, and clean-up operations of the Government in air pollution cases, guarantee restoration of ecosystems and

rehabilitate areas affected by violations of the law; and

- Air Pollution Research and Development Program, led by DOST, which will develop air quality guideline values and standards in addition to internationally accepted standards.

Permit regulations and air pollution clearances for stationary sources are described in DAO 2000-81, the IRR of RA 8479. The issuance states that all stationary sources of air pollution subject to the IRR, which can include TSD facilities, must have a valid Permit to Operate issued by the Director of the DENR EMB. This will cover emission limitations for regulated air pollutants such as mercury, which has a maximum permissible limit of 5 mg Hg/ Ncm. The law also specifically bans incineration for hazardous wastes.

2.4.4 RA 9275 – An Act Providing for a Comprehensive Water Quality Management

RA 9275, also known as the Philippine Clean Water Act of 2004, mandates the government to formulate a holistic national program for water quality management. This includes:

1. Streamlining processes and procedures in the prevention, control and abatement of pollution of the country's water resources;

2. Promoting environmental strategies economic instruments and control mechanisms for the protection of water resources, with a priority for pollution prevention measures;

3. Promoting commercial and industrial processes and products that are environment friendly and energy efficient;

4. Encouraging cooperation and self-regulation among citizens and industries through the application of market-based instruments;

5. Promoting public information and education, as well as the participation of the public and other stakeholders in water quality planning and monitoring; and

6. Accountability for environmental impacts caused by any activity, through the establishment of an environmental guarantee fund or mechanism.

To achieve these, the law created a water quality management system composed of the following:

- Designation of Water Quality Management Areas and non-attainment areas

- Creation of a National Sewerage and Septage Management Program

- Creation of a National Water Quality Management Fund, and Area Water Quality Management Fund;

- Financial liability mechanism, in the form of an environmental guarantee fund and programmatic environmental impact assessment;

- Pollution Research and Development Program

Discharge permits are further described in DAO 2005-10, the IRR of RA 8479. The issuance states that all owners or operators of facilities that discharge regulated effluents must have a valid discharge permit which specify the quantity and quality of effluent that said facilities are allowed to discharge into a particular water body, as well as the compliance schedule and monitoring requirements. Meanwhile, DAO 2016-08 provides the Water Quality Guidelines (WQG) and General Effluent Standards (GES) pursuant to RA 8479. The WQG includes the primary parameters or required water quality parameters to be monitored for water bodies in the Philippines, while secondary parameters are used as part of baseline assessment for environmental impact assessments (EIAs). Mercury is included as part of the secondary parameters, and have the following WQG values (Table 5):

Table 5 **WQG values for mercury as per DAO 2016-08**

Water Body Classification		Values (mg/L)
	Freshwater	
AA	Public water supply class I	0.001
A	Public water supply class II	0.001
B	Recreational water class I	0.001
C	Recreational water class II Fishery water for propagation Water for agriculture, irrigation and livestock watering	0.002
D	Navigable waters	0.004
	Marine	
SA	Protected waters and fishery water class I	0.001
SB	Fishery water class II Tourist zones Recreational water class I	0.001
SC	Fishery water class III Recreational water class II Fish and wildlife sanctuaries	0.002
SD	Navigable waters	0.004

2.4.5 PD 1586 – Establishing an Environmental Impact Statement (EIS) System Including Other Environmental Management Related Measures and for other Purposes

Presidential Decree 1586 articulates the establishment of an EIS System covering all agencies and instrumentalities of the national government, including government-owned or controlled corporations, as well as private corporations, firms and entities, for every proposed project and undertaking which significantly affect the quality of the environment. This includes the regulatory requirements for the conduct of an environmental impact assessment (EIA), as well as the recognition of projects and areas that can be considered as environmentally critical and would require an EIA.

By virtue of Proclamation 2146 issued in 1986, these project and areas would later be called Environmentally Critical Projects (ECPs) and Environmentally Critical Areas (ECAs), requiring environmental compliance certificate (ECC) application from the then National Environmental Protection Council (NEPC), now assumed by the DENR EMB. The IRR of PD 1586 have undergone several iterations, with the latest being DAO 2003-30. The IRR contains specific criteria for determining projects or undertakings to be covered by the EIS system, the specific requirements for securing an ECC, and the guidelines for other documents required under the EIS system such as the Environmental Impact Statement (EIS), the Programmatic Environmental Impact Statement (PEIS), and the Initial Environmental Examination (IEE) Report, as well as the Environmental Performance Report and Management Plan (EPRMP), among others. Given on the nature of the TSD facility and/or the area in which it will be located, requirements under the EIS system should be complied with.

Guidelines on monitoring projects with ECCs are likewise provided in DAO 2003-30 including requirements for the creation of a Multipartite Monitoring Team (MMT) especially for projects classified under Category A, self-monitoring, and third-party audits. The creation of an Environmental Guarantee Fund (EGF) is required for all co-located or single projects that have been determined by DENR to pose a significant public risk or where the project requires rehabilitation or restoration. Moreover, an EGF Committee composed of representatives from the EMB Central Office, EMB Regional Office, affected communities, concerned LGU's, and relevant

government agencies identified by EMB shall be formed to manage the fund, defined by an integrated Memorandum of Agreement (MOA) among all parties involved.

2.4.6 DOH-led and Other Policies Regulating Mercury

2.4.6.1 RA 9711 – An Act Strengthening and Rationalizing the Regulatory Capacity of the Bureau of Food and Drugs (BFAD) by Establishing Adequate Testing Laboratories and Field Offices, Upgrading its Equipment, Augmenting its Human Resource Complement, Giving Authority to Retain Its Income, Renaming it the Food and Drug Administration (FDA), Amending Certain Sections of Republic Act No 3720, As Amended, and Appropriating Funds Thereof

Also known as the Food and Drug Administration (FDA) Act of 2009, RA 9711 aims to enhance and strengthen the administrative and technical capacity of the FDA in the regulation of establishments and products under its jurisdiction. It builds on the provisions of previous laws such as RA 3720, enacted in 1963, Executive Order No. 175 (which amended RA 3720) and Executive Order No. 102 which created the Bureau of Health Devices and Technology to regulate medical devices.

RA 9711 paved the way for the establishment of the four centers of FDA, one of which is the Center for Device Regulation, Radiation Health, and Research (CDRRHR), which has the following functions, among others:

1. Regulation of the manufacture, import, export, distribution, promotion, advertisement, and sale of medical devices, radiation devices and health-related devices;

2. Health technology assessment of medical devices;

3. Standards formulation; and

4. Post-market surveillance (compliance monitoring).

They define medical devices as "*any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or similar or related article: (a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:*

- *Diagnosis, prevention, monitoring, treatment or alleviation od disease,*

- *Diagnosis, monitoring, treatment, alleviation of or compensation for an injury....*

The FDA regulates medical device products through the issuance of certificates of product registration (CPR), and the medical device establishment (i.e., distributor, importer, wholesaler, exporter, manufacturer), through the issuance of licenses to operate (LTO). Currently, thermometers are included in the list of medical devices requiring registration. Included in the list of requirements for the issuance of the CPR are the technical specification and physical description of the finished product, labeling materials to be used, and risk management measures.

Due to reports of the illegal sale of mercury-containing thermometers and sphygmomanometers in online marketplaces at the height of the COVID-19 pandemic (e.g., Ramos, 2020), the CDRRHR committed to facilitate the development of a policy reiterating the ban on MCMMDs. The draft circular aims to ban the manufacture, distribution, importation/ export, sale/ offer for sale (including through digital platforms), donation, transfer, use, and promotion/ advertising/ sponsorship of MCMMDs. This means that manufacturers, traders, distributors, importers, exporters and/ or wholesalers must undertake an inventory of stock and recall the concerned products to ensure that they are removed from the market. The concerning parties must also comply with the existing rules and regulations of the DENR regarding the storage, transport, and disposal of the banned medical devices. The circular is expected to take effect within the year.

2.4.6.2 DOH AO 2008-21 – Gradual Phase-Out of Mercury in All Philippine Healthcare Facilities and Institutions

DOH AO 2008-21 provides the policies and guidelines for a two-year phase-out on the use of mercury in all healthcare facilities pursuant to the provisions of RA 6969, DAO 1992-29, DAO 1997-38, and other relevant laws and regulations. It applies to all health care facilities and institutions, including hospitals, infirmaries, birthing homes, and clinics.

Recognizing the risks posed by the continued use of mercury-containing products, DOH AO 2008-21 sets forth the immediate discontinuation of the distribution of mercury thermometers to patients as part of the hospitals admission/discharge kits. It also requires all hospitals to follow the guidelines for the gradual phase-out of mercury in health care facilities.

For new health care facilities, DOH AO 2008-21 requires the submission of an inventory of all mercury-containing devices to be used and a corresponding mercury elimination program. All health care facilities other than hospitals are also required to make a Mercury Minimization Program based on a set of guidelines set by the Order. Furthermore, DOH AO 2008-21 requires the designation of the Mercury Management Team under the Hospital Waste Management Committee in all health care facilities. The Mercury Management Team in each health care facility shall have accomplished the following for the first six months of their inception:

- Conduct of a Mercury Audit of their facility, including assessment of costs of switching to alternative devices;
- Development and management of a Mercury Minimization Program;
- Drafting and implementation of a purchasing policy requiring vendors to sign a mercury-content disclosure agreement that covers products intended for purchase and communicate to suppliers the eventual mercury-free purchasing policy;
- Conduct of a facility-wide information campaign and employee education on the consequences of mercury-use as well as the accomplishment of personnel training on preventing and proper handling of mercury spills; and
- Identification and removal of unnecessary practices that promote the use and distribution of mercury-containing medical devices.

Lastly, DOH AO 2008-21 sets a clear timeline on the implementation of the phase-out program. It states that, within 24 months from its effectivity, all hospitals should have accomplished the following:

- Full implementation of the Mercury Minimization Program
- Switch from mercury-containing devices to alternatives
- Development and implementation of waste segregation and recycling program to further reduce mercury waste stream for cases where no alternative products exist (e.g. mercury-containing batteries and fluorescent light bulbs)
- Identification of a mercury collection area within the facility
- Development of proper temporary mercury storage room in the facility that is not accessible to the public;
- Incorporation of mercury management module in the training program for new personnel; and
- Display of information materials on mercury for the benefit of the patients and the general program.

DOH AO 2008-21 are further disseminated in schools through the DILG MC 2010-140, enjoining LGUs to comply with the AO, as well as DepEd MC 2010-160, which restates the same requirements to all public and private schools in the Philippines.

Table 6 **Mercury-related indicators in the Philhealth benchbook for healthcare facility accreditation**

Code	Standards	Criteria	Indicator	Evidence	Section
6.1.2.a.1	The organization provides a safe and effective environment of care consistent with its mission and services, and with laws and regulations	Policies and procedures that address safety, security, control of hazardous materials and biological wastes, emergency and disaster preparedness, fire safety, radiation safety and utility systems are documented and implemented	Presence of policies and procedures that address safety, security, control of hazardous materials and biological wastes, emergency and disaster preparedness and safety, radiation safety and utility systems and existence of safety programs on… 2. medical device safety 3. chemical safety 8. waste management 9. hospital safety program	Document review Policies and procedures that address the following: … 3. Control of hazardous materials and biological wastes (including the gradual phaseout of mercury) Existence of safety programs such as: … 2. medical device safety 3. chemical safety 8. waste management 9. hospital safety program	Document review Leadership interview
6.1.2.b.1 core		Policies and procedures for the safe and efficient use of medical equipment according to specifications are documented and implemented	Presence of policies and procedures for the safe and efficient use of medical equipment (CORE)	Document review Policies and procedures on the safe and efficient use of medical equipment (including the implementation of DOH AO 2008-21 on the gradual phase out of mercury	Document review

Meanwhile, Philhealth integrated the provisions of the AO in their benchbook for accreditation of healthcare facilities. The indicators and sources of verification identified by Philhealth include (Table 6).

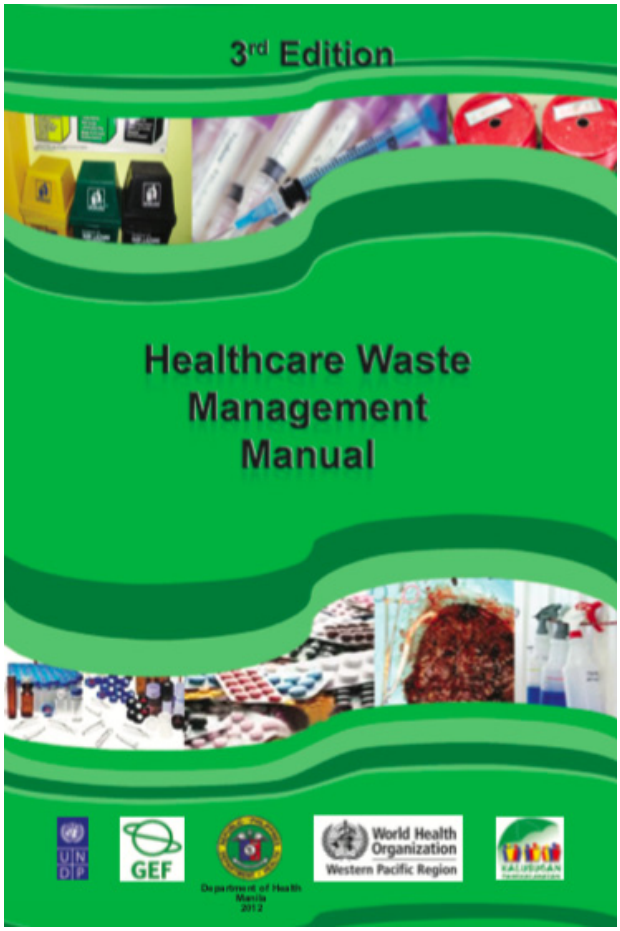
In 2017, DOH released Department Memorandum (DM) 2017-0302, indicating that all temporarily stored on-site mercury wastes such as MCMMDs be disposed through accredited transporters and TSD facilities of DENR EMB. Specific service providers identified in the memorandum were FRP Philippines Corporation and Cleanway Environmental Solutions, Inc.

2.4.6.3 DOH Healthcare Waste Management Manual

To further facilitate the management of healthcare waste in the country, the DOH developed a manual providing guidelines on the generation, handling, storage, treatment, and disposal of healthcare wastes targeting individuals responsible for overseeing the healthcare waste stream. Specifically, the manual categorizes MCMMDs under "*wastes with high content of heavy metals*", which are described as typically generated by spillage of broken clinical equipment (e.g., thermometers, blood pressure gauges, etc. According to the manual,

- Healthcare waste minimization is at the center of the elimination of the healthcare waste stream. This includes replacing, for example, mercury thermometers with digital electronic thermometers;
- Segregating mercury waste from the general waste;
- Sending the collected mercury waste to a waste treatment facility available in the area;
- Exemption of mercury in the list of wastes that can undergo pyrolysis or treatment in an autoclave;
- Recovery of spilled mercury by an authorized personnel or pollution control officer;

Figure 2 **DOH Healthcare Waste Management Manual**



2.4.6.4 JAO 2005-02 – Policies and Guidelines on the Effective and Proper Handling, Collection, Transport, Treatment, Storage and Disposal of Healthcare Wastes

In line with RA 6969, RA 9003, RA 8749, RA 9275, PD 1586, among others, DENR and DOH issued a joint AO to provide guidelines for the management of biological and hazardous wastes generated from health care facilities. It covers all healthcare waste generators, defined as all healthcare facilities, institutions, business establishments and other similar healthcare services with activities or work processes that generate healthcare waste.

Furthermore, it clarifies the jurisdiction, authority, and responsibilities between DENR and DOH with the aim of harmonizing the efforts of DENR and DOH on proper health care waste management. The DENR-EMB is recognized as the primary government agency responsible for implementing the pertinent rules and regulations on the management of healthcare waste in the Philippines, as governed by the aforementioned national legislations. It will be responsible for formulating policies and standards; overseeing compliance of generators, transporters and TSD facility operators; among others, and will be notifying DOH on cases of non-compliance or violation. Meanwhile, the DOH Bureau of Health Facilities and Services (now the Health Facilities and Services Regulatory Bureau HFSRB), will regulate all hospitals and other health facilities through licensure and accreditation under RA 4226 or the Hospital Licensure Act; formulate policies and standards on the management of healthcare waste; develop training programs and modules; and provide technical assistance in the preparation of healthcare waste management plans. DOH Centers for Health Development (CHDs) are also mandated to advocate for healthcare waste management (HCWM) practices to local chief executives and other stakeholders; monitor HCWM practices in all healthcare facilities within their jurisdictions; and provide them with technical assistance.

Table 7 **Mercury-related indicators in the DOH HFSRB assessment tool for licensing hospitals**

Criteria	Indicator	Evidence	Areas
44. Policies and procedures for the safe and efficient use of medical equipment according to specifications are documented and implemented	Presence of policies and procedures for: ▪ - quality control ▪ - corrective and preventive maintenance program for medical equipment	Document review: 1. Presence of operating manuals of the medical equipment 2. Preventive and corrective maintenance logbook 3. Film reject analysis 4. Quality control tests results Observe: How staff performs necessary precaution or safety procedures such as… Note: Look into their storage of mercury containing devices which are no longer allowed to be used	ER OPD Wards DR Laboratory Pharmacy Maintenance office Other areas

Under the JAO, healthcare waste generators are required to apply for an ECC, permit to operate and discharge permit from the DENR EMB, along with registering as a hazardous waste generator under DAO 2004-36 (now DAO 2013-22). They will also need to apply for a license to operate from DOH HFSRB. The assessment tool used by the HFSRB for level 1 hospital licensure notes the following mercury-related indicators (Table 7):

Meanwhile, handling, collection, storage, and treatment, storage and disposal of mercury-containing health care wastes should be in accordance with the requirements of RA 6969, RA 8749, RA 9003, and the revised DOH Health Care Waste Management Manual.

2.4.7 National Action Plan for the Phaseout of MAPs and the Management of the Associated Mercury-Containing Wastes

In 2019, the DENR, in partnership with UNIDO, developed the National Action Plan (NAP), which aims to detail the 5-year implementation plan for the ESM of mercury-containing products in accordance with the provisions of the Minamata and Basel Conventions. It outlines the responsibilities of government agencies involved in the inter-agency technical working group (IATWG) such as the DENR, DOH, FDA, DOLE, DOE, DTI, DILG, DOST, DOF - Bureau of Customs (BOC), FPA, DepEd, Commission on Higher Education (CHED), as well as civil society organizations, on five key intervention areas:

1. Policy;
2. Strengthening capacities;
3. Quality data and evidence;
4. Innovation and implementation; and
5. Partnerships advocacy.

Specifically for MCMMDs, the NAP includes the following activities and timelines:

Table 8 **NAP activities relevant to MCMMDs**

Specific Activities	Timeline	Lead Agency	Budget Required
1. Policy			
1.1 Gap analysis of existing policies	Q2 2020	IATWG	PHP 5.3 million
1.2-1.4 Issuance of draft policies	Draft – Q3 2019 Finalization – Q1 2020 Dissemination – Q2 2020	DENR (revised CCO) DOH-FDA (circular on MCMMDs)	Part of the regular operations of the agencies
1.5 Expand advance PCO training	Q4 2020	DENR	Part of the regular operations of the agencies
1.6 Review implementation of NAP; update action plan	Q3 2019	DENR	Part of the regular operations of the agencies
1.7 Enhance public health programs	Q4 2019	DOH	Part of the regular operations of the agencies
1.8 FDA circular on MAPs sold online	Q3 2020	FDA	Part of the regular operations of the agencies
1.9 Deped to update K-12 curriculum to integrate ESM of chemicals and wastes	Until 2021	DepEd (and CHED)	Part of the regular operations of the agencies
1.13 Prepare incentive program to recognize mercury-free settings	Q4 2020	IATWG	PHP 3 million
2. Strengthening capacities			
2.1 Institutionalize TWG for MAPs	Q3 2020	DENR	PHP 1.5 million
2.5 Training on ESM of MAPs	Q4 2020	DENR	PHP 2 million
2.7 Prepare health promotion program related to MAPs and mercury	Q4 2020	DOH	PHP 1 million
2.8 Develop risk assessment modules for regional offices	Q4 2020	DOH	PHP 1.2 million
2.9 Develop capacity building programs to promote safety and health of workers	Q4 2020	DOLE OSHC	PHP 2 million
3. Quality data and evidence			
3.2 M&E of NAP activities	Until Q4 2023	DENR	PHP 2 million
4. Innovation/ implementation			
4.1 MOA for monitoring of MAPs	Q4 2021	IATWG	Part of the regular operations of the agencies
4.2 MOA on interim storage-interagency and up to disposal	Q4 2021	IATWG	Part of the regular operations of the agencies
4.2.1 Establishment of storage facility of confiscated MAP	Q1 2022 (upon ratification)	FDA, others	PHP 50 million
5. Partnerships and advocacy			
5.2 Dissemination of NAP to key stakeholders	Q4 2019	DENR	PHP 500 thousand
5.3-5.4 Development of communication plan	Q4 2019	DENR	PHP 500 thousand
5.5 Recognition and award system for mercury-free stings	Annual	IATWG	Part of the regular operations of the agencies

INTERNATIONAL GUIDELINES AND BEST PRACTICES FOR THE ENVIRONMENTALLY SOUND MANAGEMENT OF MERCURY-CONTAINING MEDICAL MEASURING DEVICES

3.1 GENERAL INFORMATION

Mercury, represented by the symbol Hg, is a naturally occurring element that can neither be created nor destroyed. It exists in several forms, namely: (1) elemental/ metallic mercury, (2) methylmercury, and (3) other organic or inorganic compounds. Once released to the environment, either through natural means or as a result of human activities, it cycles between air, land, and water, and bioaccumulates and biomagnifies in the food chain. Mercury is highly toxic, affecting the nervous system, brain, heart, kidneys, lungs and the immune system.

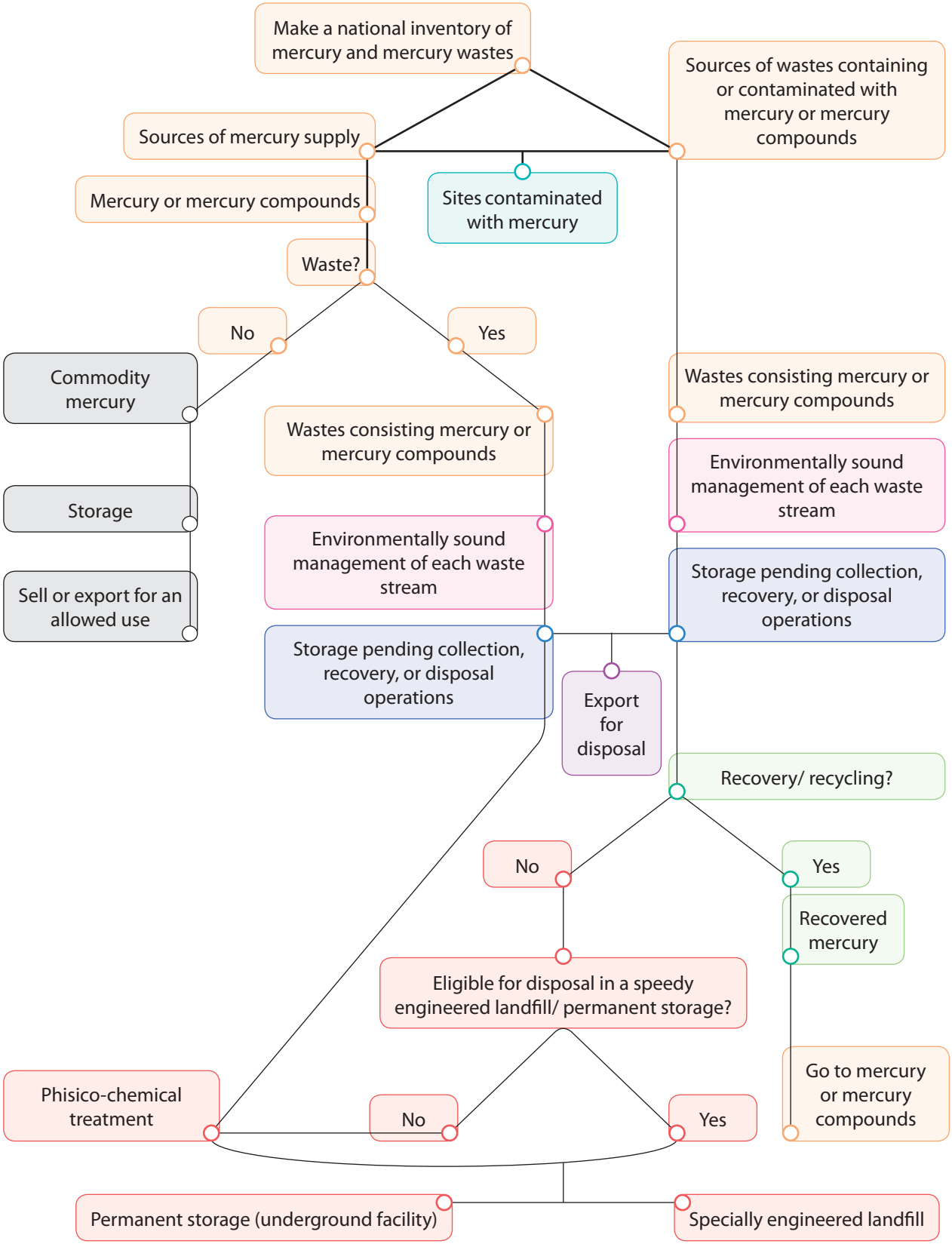
Due to the threats mercury poses to human health and the environment, it needs to be managed in an environmentally sound manner. The following subsection consolidates the requirements, guidelines, and best practices for the ESM of MCMMDs, extracted from the Minamata and Basel Conventions and other guidance documents developed by UNDP, UNEP, UNIDO, WHO, and other stakeholders. Insights gained from other national policies and programs were also included, providing a more comprehensive picture of the existing policy framework. Using the life cycle approach, the guidelines for the ESM of MCMMDs can be visualized using the flow chart shown in Figure 3.

3.2 WASTE PREVENTION AND MINIMIZATION

The prevention and minimization of mercury wastes is the first and most important step in the ESM of such wastes. Article 4 para 2 of the Basel Convention calls on Parties to "*ensure that the generation of hazardous and other wastes... is reduced to a minimum*". Waste prevention should be a priority in any waste management policy, as it reduces the need for waste management and enables resources for ESM to be used efficiently.

Specifically, the Minamata Convention prohibits the manufacture, import, and export of MCMMDs listed in its Annex A starting in 2020. This swift transition is made possible by the availability of mercury-free alternatives, which was the focus of studies years before the negotiations for the development of the Convention. For instance, in 2008, the Governing Council of UNEP established an open-ended working group (OEWG) to review and assess measures to address the global issue of mercury. Part of their efforts includes consolidating information from countries on the estimated mercury demand, level of substitution, and experience with mercury-free alternatives for six product categories including mercury thermometers and sphygmomanometers. Responses from 33 countries showed that successful transition has been demonstrated in countries where mercury-free alternatives are

Figure 3 **Flowchart for the ESM of MCMMDs[39]**



available. For thermometers, 53% of respondents indicated that alternatives are available in the market and are commonly used without any

39 Ibid. 14

Case Study 1 . Hospitals for a Healthy Environment Pledge: a voluntary pledge to phase out MC-MMDs in the United States

The American Hospital Association (AHA) is a national organization that represents and serves nearly 5,000 hospitals, healthcare networks, and their patients and communities. In 1998, the US EPA and the AHA signed a memorandum of understanding (MOU) committing to the virtual elimination of mercury from hospitals by 2005. This involved the formation of multi-stakeholder workgroups; creating and administering data collection surveys to establish a baseline; developing a clearing house of technical assistance providers; creating training programs and informational materials; and initiating a pledge program for hospitals to pledge to be a "Hospital for a Healthy Environment" and work to reduce the waste they generate in treating patients.

Case Study 2 Phase out regulations for MCMMDs in Europe

After considerable pressure from civil society organizations, the EU prohibited the sale of mercury thermometers and sphygmomanometers to the general public starting in 2008. This move is part of the comprehensive strategy adopted by the European Commission starting in 2005, which included (HCWH, 2007):

- Prohibition on the marketing and sale of MCMMDs for domestic use and in healthcare settings;
- Commitment to ban the export of mercury from EU countries by 2011;
- Regulatory measures to reduce mercury use in dental amalgam and ensure its proper disposal;
- Improved biomonitoring of vulnerable groups; and
- Support for international action on mercury.

negative consequences (Table 9). Further, five countries reported zero demand for mercury-containing thermometers, although four countries reported that the costs were higher for the mercury-free alternatives. Meanwhile, 69% of the respondents indicated that mercury-free sphygmomanometers are available in the market and are commonly used without any negative experiences (Table 10).

The OEWG study showed that mercury-free alternatives are available, however, the accuracy and quality of these devices need to be explored, especially in low- and middle-income countries. to address this, the WHO developed several documents outlining the "Technical Specifications" for medical devices such as thermometers and sphygmomanometers. These Technical Specifications enumerate the characteristics, regulatory requirements and standards, calibration and maintenance procedures of these devices, as well as guidance for their procurement, decontamination and decommissioning. Annex A contains the WHO technical specifications for digital and infrared thermometers while Annex B contains the WHO technical specifications for manual and automated sphygmomanometers.

These Technical Specifications can be used as a reference in procurement programs aimed at securing mercury-free products. WHO asserts that "*procurement is a vital element of equitable access to healthcare*", and is defined as the "*acquisition of property, plant and/or equipment, goods, works or services through purchase, hire, lease, rental or exchange*". Procurement includes "*all actions from planning and forecasting, identification of needs, sourcing and solicitation of offers, evaluation of offers, review and award of contracts, contracting and all phases of contract administration until delivery of the goods, the end of a contract, or the useful life of an asset*"—thereby covering the whole life cycle of medical healthcare assets (Figure 4).

Table 9 **Comparison of different types of thermometers**[40]

Type	Mercury	Alcohol
Brief description	A glass tube is filled with mercury and a standard temperature scale is marked on the tube	An organic is contained in a glass bulb which is connected to a capillary of the same glass. The space above the liquid is a mixture of nitrogen and the vapor of the liquid.
Method of temperature estimation	With changes in temperature, the mercury/ liquid expands and contracts, and the temperature can be read from the scale	
Advantages	▪ Good conductor of heat, can measure high temperatures ▪ Give results quickly ▪ Does not wet the wall of the thermometer, thus, can be highly accurate	▪ Suitable for low temperatures ▪ Less toxic ▪ Has greater value of temperature coefficient
Disadvantages	▪ Mercury is an environmental hazard ▪ Cannot measure cold temperatures ▪ Has low thermal coefficient	▪ Cannot measure high temperature because of low boiling point ▪ Wets the wall of the thermometer, which can impact accuracy of readings

Table 10 **Comparison of different types of sphygmomanometers**[41]

Type	Manual/ analogue	
	Mercury	Aneroid
Brief description	Pressure cuff, hand pump, mercury column, stethoscope	Pressure cuff, hand pump, aneroid (mechanical transducer), stethoscope
Method of blood pressure estimation	Detection of Korotkoff sounds through a stethoscope for auscultation.	
Advantages	▪ No need for calibration, inexpensive, does not require electricity	▪ Inexpensive and portable ▪ Does not require electricity

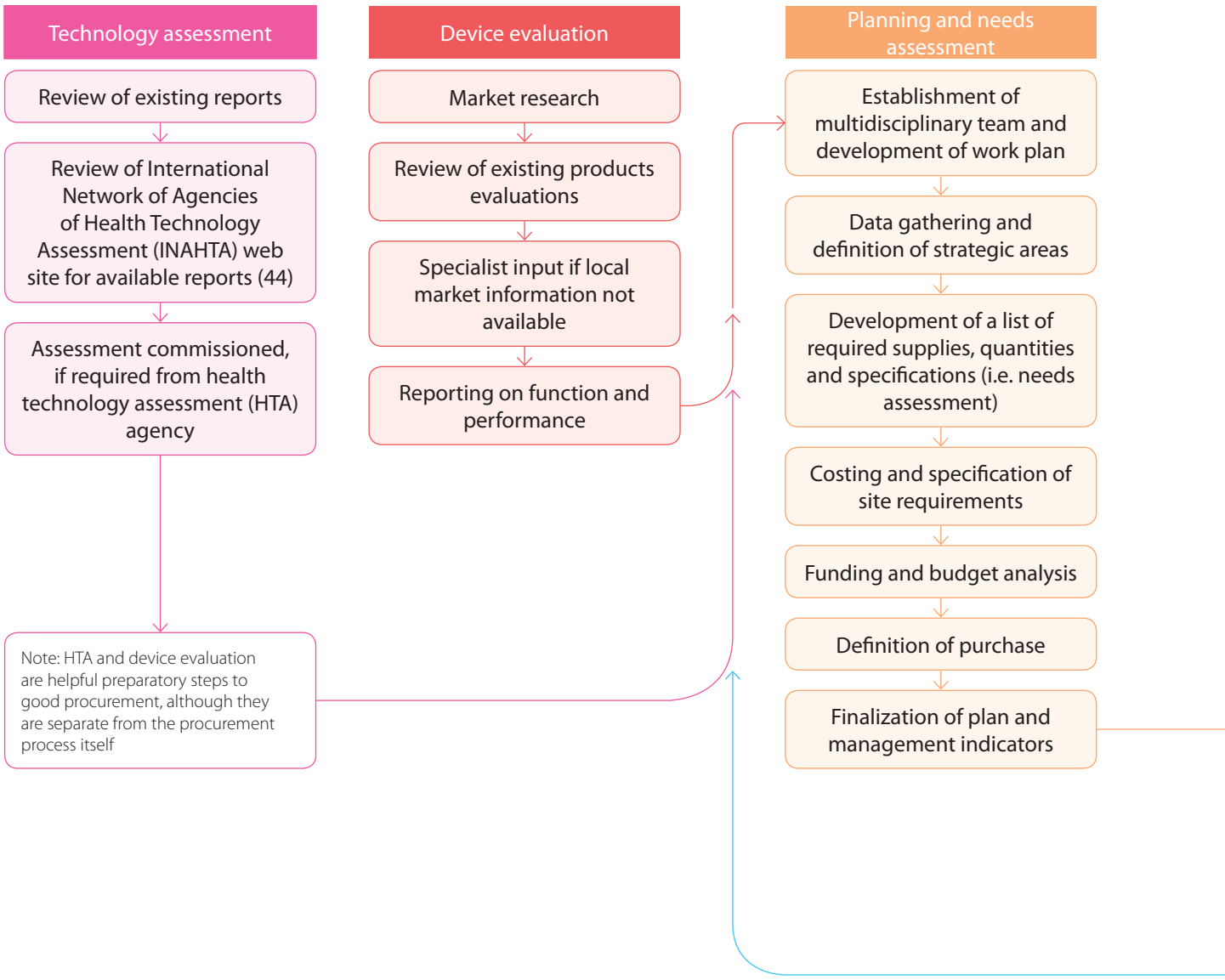
40 Ibid. 30
41 Ibid. 29

	Digital	Digital Infrared
	It may comprise an electronic unit with an attached probe or be a single unit that detects and converts the changes in temperature into variations of some electrical characteristic. These variations of the electrical characteristics are processed in the electronic circuits and in turn displayed, for a short period, as temperature readings.	Consist of an infrared probe, electronic circuitry, a microprocessor, and an LCD or LED display
		Probes are made up of electronic thermal radiation transducers and waveguides. The radiation collected by the waveguide is converted to an electrical signal by the transducer and displayed as a temperature reading.
	Inexpensive, easy to read, require very little maintenance and give an accurate reading	▪ Allows for no contact option ▪ Takes quick measurement
	▪ Gets damaged easily if dropped ▪ Requires batteries/ electricity	▪ Not as accurate as contact measurements ▪ If used for tympanic measurement, for example, presence of ear wax can affect readings

	Electronic/ automated			
	Semi-automated, cuff	Automated, cuff		Cuffless technique, mobile app
	Pressure cuff, hand pump to inflate cuff, automated deflation and determination of BP	Pressure cuff automatically inflates and deflates to determine one BP	Pressure cuff automatically inflates and deflates to determine multiple BP after a predetermined period of rest and with a predetermined pause between repeated measurements. All measurements ± an average of measurements is displayed.	E.g. tonometry, pulse transit time, ultrasound or magnetic method, tissue characteristic methods, machine-learning methods, heart rate variation and heartrate power spectrum ratio, photoplethysmography, heart rate and smartphone technology
	Most common: Detection of arterial flow (oscillometry), in which pulses sensed through the cuff are filtered, amplified, processed and applied to an algorithm to estimate systolic and diastolic BP. Least common: Detection of Korotkoff sounds by the device with a pressure transducer (auscultatory), which are then used to estimate BP			Variable
	▪ Portable ▪ Easy to use ▪ Has fewer observer errors ▪ Minimal observer bias or terminal digit preference ▪ Good for screening, home use ▪ Saves time for clinical resources ▪ Less expertise and training required when used in the absence of a healthcare provider ▪ Calibration not required			▪ Can measure during motion or continuously ▪ Easy measurement without discomfort

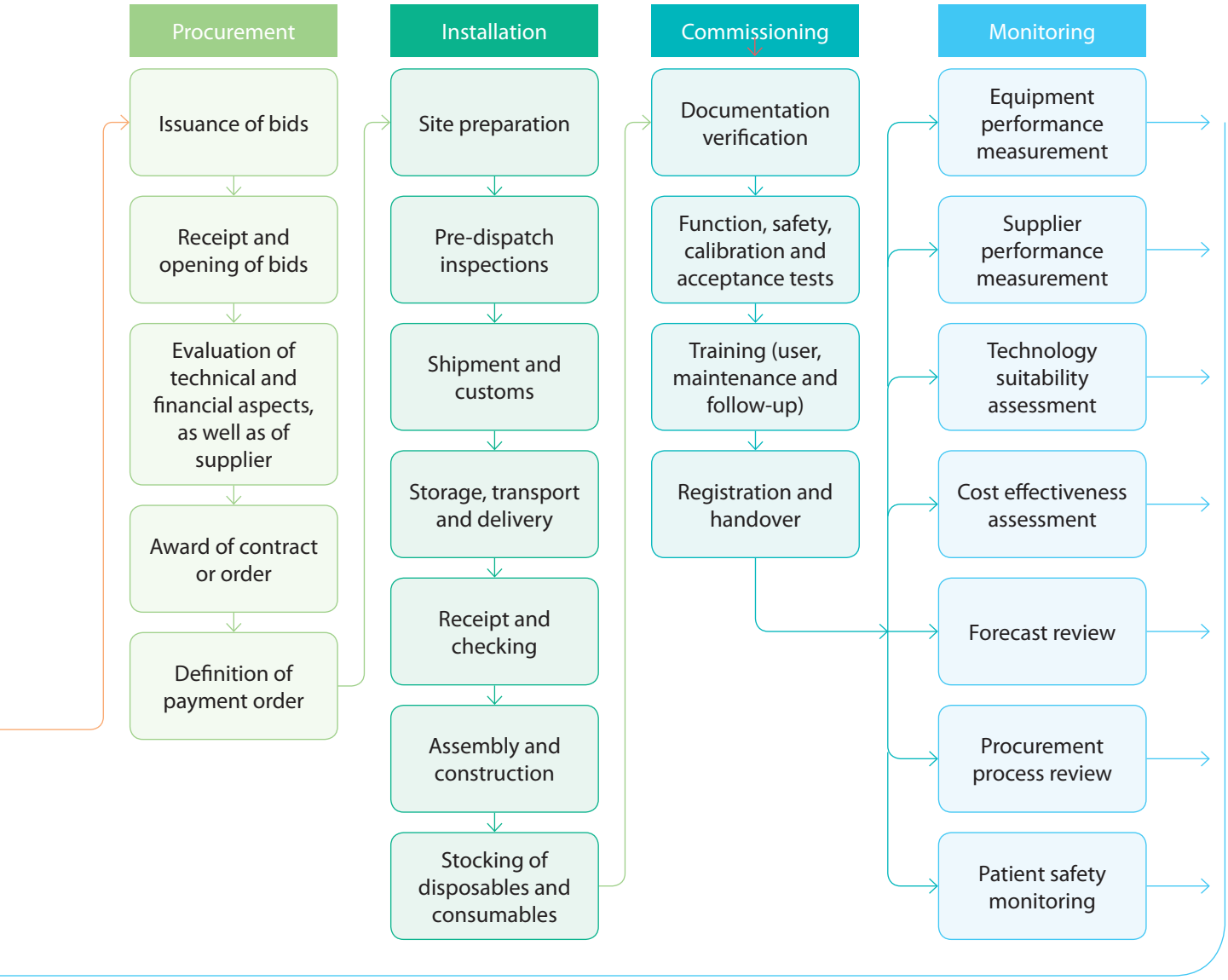
Type	Manual/ analogue		
	Mercury	Aneroid	
Disadvantages	▪ Risk of noise interference ▪ Expertise and retraining required to avoid observer error ▪ Requires manual dexterity to ensure proper cuff deflation rate ▪ Risk of observer bias and terminal digit preference ▪ Requires excellent hearing and vision		
	Mercury is an environmental hazard	▪ Requires regular calibration ▪ A device can lose calibration when jostled or bumped ▪ Often inaccurate in clinical practice if no routine accuracy testing	

Figure 4 **Regional Response Rates - National Survey[42]**



42 Ibid. 23

	Electronic/ automated		
	Semi-automated, cuff	Automated, cuff	Cuffless technique, mobile app
	▪ Requires access to a continuous power source (electricity or battery) Requires validation by standard protocol (some are validated only for adults) ▪ Manufacturer variation due to proprietary algorithm for estimation Some are inaccurate Cost and longevity of device Integrity of cuff and tubing essential to maintain accuracy over time Must be replaced periodically because of mechanical failure		▪ Generally poor accuracy, more trials are needed ▪ No current accuracy standards; devices need to be tested to ensure accuracy
	Requires manual inflation of cuff, which can lead to false measurements if cuff not fully inflated	Many are not suitable for patients with atrial fibrillation	



Following this framework, the successful replacement of MCMMDs in healthcare settings will entail:

1. Involving participatory stakeholders, such as the medical and nursing staff, heads of departments where MCMMDs are commonly used and the departments involved in budgeting and planning. Promulgate institutional policies regarding the phase out of mercury, as appropriate.

2. Conducting an inventory to identify the numbers and uses of mercury-containing devices and materials, as well as to determine the disposal practices.

3. Evaluating the feasibility and acceptability of mercury-free alternatives. Consultations with healthcare providers about which types of devices are appropriate to accommodate the age of the patients, their medical conditions, the institutional setting, portability, sterilization process, ease of use, safety and patient comfort are crucial. In addition, costs, time spent for temperature measurement, storage requirements and uniformity can be institutional considerations.

4. Identifying vendors and planning the phase out of MCMMDs and phase in of mercury-free alternatives. If possible, ask vendors to provide trail units and evaluate them in areas where they will be used.

5. Developing a budget and procurement process, including the resources needed for purchase of units and accessories, installation, staff training or education, calibration and maintenance. Budget requirements for the removal and storage of MCMMDs must be considered.

6. Developing a bid specification for the purchase of the replacement units, including the number of units to be required. More information on the technical specifications of the devices are provided in Annex A and B, which can be used in the bid specifications. Follow the standard procedures for competitive bidding already identified in the institution's policy. Require certification of proof of compliance with the standard.

7. Safely removing or disposing MCMMDs. Ensure that it is placed in sealed primary and secondary containers and store in an interim storage site or give to the approved mercury waste disposal facility identified;

8. Preparing programs such as staff education;

9. Periodically maintaining and calibrating equipment as needed; and

Monitoring the use of mercury-free alternatives to ensure that they are being properly used and maintained, and that any waste, including end-of-life waste, is managed in an environmentally sound manner.

3.3 ON-SITE ASSESSMENT AND INVENTORY

Inventories are an important tool for identifying, quantifying and characterizing wastes. These can be used to establish baseline information on MAPs and mercury waste, which can assist in planning for the life cycle management of mercury and the preparation of emergency response plants.

The first step in inventories is to define wastes considered as hazardous under national legislations (Basel Convention Article 3 para 1). The Basel Convention Technical Guidelines and the Minamata Convention identify three categories of mercury wastes (Table 11). Specifically, Article 11 para 2 of the Minamata Convention notes that only those wastes consisting of, containing or contaminated with mercury or mercury compounds in a quantity above the relevant thresholds defined by the Conference of the Parties (COP) to the Convention will be defined as mercury wastes. However, the COP decided at its 3rd meeting in 2019 that no thresholds need to be established for mercury waste falling under Art. 11 para 2 (a-b) of the Convention, namely wastes consisting of and containing mercury or mercury compounds.

Table 11 **Categories of mercury wastes**[31]

Category	Examples
Wastes consisting of mercury or mercury compounds	▪ Excess mercury from the decommissioning of chlor-alkali facilities; ▪ Mercury recovered from: ‣ wastes containing mercury or mercury compounds ‣ wastes contaminated with mercury or mercury compounds ▪ Surplus stock of mercury or mercury compounds designated as waste.
Wastes containing mercury or mercury compounds	▪ Wastes of products containing mercury or mercury compounds that easily release mercury into the environment including when they are broken (e.g. mercury thermometers, fluorescent lamps); ▪ Other wastes of products containing mercury (e.g. batteries);
Wastes contaminated with mercury or mercury compounds	▪ Residues generated from mining processes, industrial processes or waste treatment processes

Reference materials that can be used for the conduct of inventories include the Methodological Guide for the Undertaking of National Inventories of Hazardous Wastes under the Basel Convention ("Methodological Guide"), and the Toolkit for the Identification and Quantification of Mercury Releases ("UNEP Toolkit"). The former provides a road map for conducting an initial national inventory of hazardous wastes. It discusses some of the challenges faced, provides guidance and proposes good practices in overcoming common obstacles. The revised guide has been adopted by the COP to the Basel Convention at its 12th meeting in May 2015. Meanwhile, the UNEP Toolkit provides a standardized methodology to enable the development of national and regional mercury inventories and incorporates estimates of the potential risks of mercury emissions and releases into the environment from different types of wastes. It exists in two versions: 'Inventory Level 1' provides a simplified version of the Toolkit to make the development of an overview inventory easier. 'Inventory Level 2' is the comprehensive version and is useful if more detailed information on specific release sources is needed. UNEP and the United Nations Institute for Training and Research (UNITAR) launched the 'MercuryLearn' online training modules to support countries in developing national mercury inventories.[43]

Mercury-containing thermometers and sphygmomanometers fall under wastes **containing** mercury or mercury compounds. However, once mercury from MAPs have been recovered through processes/ operations discussed in the Basel Convention Technical Guidelines, they can be classified as wastes **consisting** of mercury or mercury compounds intended for environmentally sound management (see Figure 3).

3.4 PACKAGING

Guidelines for packaging and labelling of hazardous wastes should be included in national legislations. In general, unbroken MCMMDs should be stored in a manner that reduces the potential for their breakage. In addition,

- Since mercury devices may break during storage or transport, the primary container must be damage-resistant and air-tight. If the original transport case or box which the devices were shipped in is still in good condition, this can be used for unbroken devices.

- As a redundant safety measure, the primary container should be placed in a secondary container that prevents release of mercury vapor in case the mercury devices break. This can be filled with plastic bubble wrap or plastic packing foam to prevent breakage. Other filling materials include bentonite clay, kaolinite and vermiculite (Figure 6).

- Both primary and secondary containers must be labelled with the type of mercury device,

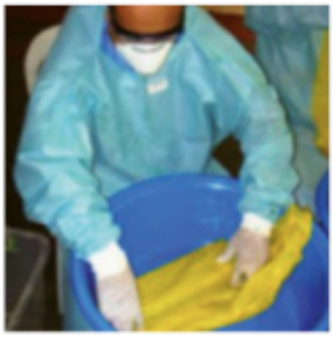
43 Ibid. 14

Figure 5 **Storage of MAPs in San Lazaro Hospital**[44]

STEP 1

Placed in the original box and sealed with duct tape

STEP 2



Wrapped in a labelled plastic bag as primary container

STEP 3

Placed in a labelled secondary container and sealed with duct tape

the quantities inside the container, the initial date of storage, and any additional description if necessary.

In cases of transboundary movement, mercury wastes should be identified, packaged and transported in accordance with the UN Recommendations on the Transport of Dangerous Goods: Model Regulations, International maritime Dangerous Goods Code, Technical Instructions for the Safe Transport of Dangerous Goods by Air, and Dangerous Goods Regulation.

3.5 LABELLING

Meanwhile, labelling is necessary to ensure the separation of mercury wastes from other wastes, and to clearly communicate the hazard of the wastes during transport. International standards have been developed for the proper labelling and identification of wastes, such as the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals and the Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. This means that the containers have the following relevant hazard pictograms and have a distinctive mark indicating, among others (Figure 6):

Figure 5 **GHS hazard pictograms for mercury wastesl**[45]

GHS06-Acute toxicity

GHS06-Acute toxicity

GHS06-Acute toxicity

44 Ibid. 14

45 Ibid. 14

3.6 TEMPORARY STORAGE AT HEALTHCARE FACILITIES

On-site storage at healthcare facilities or at collection sites. End-of-life MAPs may be stored for a short period of time before transport to a centralized facility or directly to a treatment facility. The containers containing the waste mercury is placed in a well-ventilated area inside buildings or outside the building in a covered and protected area. The following general guidelines must be considered for on-site storage:

- The storage area must be located in a secure, restricted area (e.g., locked room or locked partition space). It must be readily accessible to authorized personnel responsible for collection and transport of the waste. The entrance and exit doors must be marked with warning signs (e.g., "Danger: Hazardous Mercury Waste" and the skull-and-crossbones symbol for toxic waste).

- The size of the area must be suitable for the projected type and volume of mercury waste identified during the inventory process, allowing for the proper segregation and packaging of the waste.

- Storage and space design requirements include:

  - Weather and insect-resistant roof and walls;
  - Sloping roof to drain water away from site;
  - Floor made of smooth material impervious to mercury;
  - An accessible and replaceable drain trap to capture mercury in the event of spill;
  - A ventilation system;
  - Fire alarm and suppression systems
  - Temperature control (must be cool and dry; below 25°C and 40% relative humidity)
  - Personnel protective equipment (PPE), spill kit and wash areas. (See Annex C for the complete checklist for the spill kit and the recommended cleanup procedures)

- General procedures that should be followed in using or maintaining an on-site storage area include:

  - Provision of training to all personnel involved in the collection, storage, transport and supervision of mercury waste;
  - Availability of material safety data sheet (MSDS) and international chemical safety cards. (See Annex D for a sample of the MSDS)
  - Regular (once a month) inspection to monitor leaks, corroded or broken containers, improper methods of storage, ventilation issues, etc.
  - Proper maintenance of inventory records, including information on the types of wastes, quantities in storage, and initial dates of storage.
  - Availability of site-specific procedures such as a workable emergency plan and identification of an authorized modification of safety procedures when necessary to allow emergency response personnel to act

3.7. COLLECTION

The Basel Convention Technical Guidelines (F. 3. Collection of wastes of products containing mercury or mercury compounds) and its associated guidance documents enumerate the following issues that "*need to be considered when establishing and implementing collection programs:*

- *Advertise the programs, depot location and collection time periods to all potential holders of mercury wastes;*
- *Allow enough time for the operation of collection programs;*

Case Study 3 **Coordinated collection by the Tokyo Medical Association in Japan**

The Tokyo Medical Association in Japan established an ad hoc collection system for end-of-life mercury thermometers and sphygmomanometers. Each member medical institution was encouraged to bring their devices to a designated local office and requested to pay specific fees for transportation and disposal. The Tokyo Medical Association then coordinated with local branches and waste transporters and managers to facilitate efficient collection and disposal of the devices collected.

- *Make acceptable containers and safe-transport materials available to mercury waste owners;*
- *Establish simple, low-cost mechanisms for collection*
- *Ensure the safety of all workers involved in the collection process;*
- *Ensure that programs and facilities meet all applicable legislative requirements; and*
- *Ensure the separation of mercury wastes from other waste streams.*"

To ensure that all sources of the waste MAP (e.g., large-scale generators such as hospitals and schools; small-scale generators such as households) will be able to access disposal options for their wastes, collection schemes can be established. Examples of collection schemes applicable for waste MAPs include:

1. Waste collection stations or drop off depots. End-of-life MAPs may be discarded in a specially designed container at a waste collection station or depot. Appropriate boxes or containers may be made available for public use, according to national priorities and capabilities.

2. Collection at public places (e.g., town halls and other public buildings). Collection may be done via specially designed collection vehicles or at public places or shops. Properly labelled containers should be placed in well ventilated areas or outside in a covered and protected area. Collection rates can be higher if the waste can be deposited free of charge.

3. Coordinated collection. Through partnership with business associations/ organizations, coordinated collection can be done by asking members/ member organizations to deposit their waste in a designated local branch, which will then facilitate further transport and disposal of the devices collected

4. Prepaid shipping service – Waste disposal facilities may offer a recycle-by-mail concept where waste generators purchase boxes or containers from the facility, including the cost of delivery. Waste MAPs are then placed in the box and shipped back to the recycler. This service is convenient for small quantity generators, and for those in remote locations.

The collection of end-of-life mercury-added products as well as subsequent recovery operations or disposal operations requires investment. How the costs of collection are distributed is a critical decision that national governments will need to determine. For instance, collection can be particularly challenging in the context of the Philippines due to its archipelagic nature which hampers the collection of MCMMDs from geographically isolated and disadvantage areas (GIDAs).

3.7 OFF-SITE TRANSPORTATION

Mercury wastes should be transported in an environmentally sound manner to avoid accidental spills. The following guidelines should be considered when transporting mercury wastes:

- Companies transporting wastes should be certified carriers of hazardous materials and wastes, with the regulatory authority issuing

Case Study 4 **Requirements for designated waste transporters**

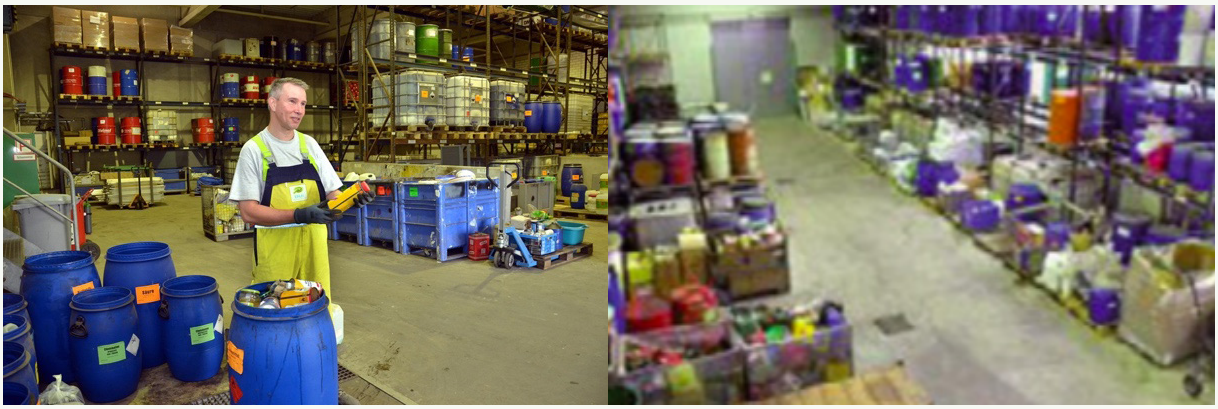
Several regulations have been developed to identify the minimum limits in which small-scale waste generators are required to contract a waste transporter. US EPA regulations 40 CFR 261.5 and regulations 49 CFR 173.164 note that small quantity generators (e.g. hospital, clinic, other health facility) can use their own vehicles when transporting less than 100 kilograms of mercury-containing waste, or 0.45 kilograms of elemental mercury, respectively. Waste quantities above this limit would require a licensed transporter and a registered vehicle.

special permits or licenses to the transporter and a special registration for the vehicle/s. The licensed transporter may be given a unique identification number or code. To obtain a license or permit to transport mercury wastes, the transporter should be asked to undergo training, submit a proof of liability insurance of guarantee bond, and provide copies of an emergency preparedness and emergency response plan, among others. In addition, the regulatory authority may opt to specify the maximum amount above which a registered transporter is required.

- Personnel involved in transporting hazardous wastes should be qualified and certified as handlers of hazardous wastes, and must have undertaken training on:
  - Legal obligations;
  - Planning, routing, handling, visual inspection, packaging, labelling, loading/ unloading, securing, placarding, manifest or consignment forms;
  - Occupational safety, hazard recognition, hazard mitigation (including ways to minimize the possibility and the consequences of accidents);
  - Use of PPE; and
  - Spill response planning, use of spill kits, emergency procedures, and accident reporting.
- A specially registered vehicle used to transport mercury waste must have the following:
  - A size suitable for the load to be transported;
  - A bulkhead between the driver's cabin and the body to retain the load in case of vehicle collision;
  - A secure system to load/ unload the wastes;
  - Empty air-tight containers, plastic bags, PPE, spill kits, cleaning equipment and decontaminating agents;
  - Markings with the names and address of the waste transporter;
  - Warning signs and placards displayed in the body of the vehicle, including the registration number.
- Contingency plans should be prepared prior to transportation to minimize environmental impacts associated with spills, fires, and other potential emergencies. The transport vehicle should also be visually inspected for any obvious leaks, spills or droplets of elemental mercury.
- All waste containers must be firmly secured to avoid tipping over during transport. It should not be stacked more than 1.5 meters high.
- A manifest system (traceability chain) must be established. The waste generator, transporter, and storage facility must have a copy of the manifest form or consignment note containing the information in the section on monitoring

Case Study 5 **Off-site storage for hazardous waste in Germany**

Figure 5 **Photo of off-site storage facility of DUL Willkommen in der Umwelt[46]**



The hazardous waste storage facility in Göppingen, Germany is a typical example of off-site storage. Operated by a local waste management service provider, the facility accepts mercury wastes from individual households and local companies and stores them for a limited amount of time until collection of certified waste disposal/ recycling facilities. Specifically, the service provider, DU: Willkommen in der Umwelt, does not charge a disposal fee for households that deliver their hazardous waste to the interim storage facility as long as the waste is within "normal household quantities".

3.8 STORAGE AT STORAGE DEPOT

Off-site storage in a centralized hazardous waste management facility, pending recovery operations or disposal. End-of-life MAPs from different sources (households, hospitals, etc.) can be collected and transported to a centralized facility. Storage may occupy a central position for countries wishing to export mercury wastes for disposal due to the lack of necessary infrastructure to ensure environmentally sound recovery/recycling, physico-chemical treatment, and/or disposal in SELs or permanent storage in underground facilities.

The following general guidelines must be considered for off-site storage:

- The storage area must be located at least 150 meters away from densely populated areas, agricultural operations, bodies of water and other environmentally sensitive areas. It must not be located in areas prone to disasters (e.g., floods, typhoons, hurricanes, bush fires, earthquakes, etc.). If possible, the facility must be located in an area with a cool climate to minimize mercury volatilization.
- It must be in a secure, restricted location to prevent theft, but must be readily accessible to trucks and other vehicles transporting mercury waste.
- The size of the area must be suitable for the projected type and volume of mercury waste and region/s being served, allowing for the proper segregation and packaging of the waste.
- The facility must be constructed to withstand or ameliorate the effects of natural disasters (e.g., seismic retrofitting, using fire-resistance materials, building in higher elevated areas, etc.).
- To reduce the risks of fire, the facility should be constructed of non-combustible materials,

46 DU: Wilkommen in der Umwelt. (2021). Services. [online]. Retrieved 21 July 2021 from https://www.du-willkommen.de/sonderabfall.html

which should be used as well for pallets, storage racks and other interior furnishings.

- The facility must have four distinct and separate areas: (1) receiving area; (2) inspection area; (3) storage area; and (4) administrative and record-keeping area.
- The receiving area is for receiving and pre-sorting waste, re-labelling if necessary and signing documents. It should include:
  - Sign to guide and instruct waste generators and transporters
  - A pre-sort table for incoming waste;
  - A separate table or counter for signing documents;
  - Cart made of impervious materials (e.g., steel, rubber or hard plastic) to be used to transfer waste to other areas.
  - Spill kits, emergency supplementary containers for leaking containers or broken packaging and PPE for staff.
- The inspection area will be used for checking for leaks, repackaging, secondary containment and re-labelling, if necessary. It should be located near the receiving and storage areas and must include:
  - Containment dikes or bunding on the floor;
  - Mercury vapor detection system (e.g., vapor monitor);
  - Local exhaust ventilation connected to a filter which removes mercury before the air is discharged;
  - Spill control or containment device;
  - Spill kits, emergency supplementary containers for leaking containers or broken packaging and PPE for staff.
- The storage area should be clearly marked with warning signs on all doors. It should have:
  - Continuous or periodic monitoring of mercury levels in ambient air;
  - Spill kits, emergency supplementary containers for leaking containers or broken packaging and PPE for staff;
  - Engineered spill control features such as a floor sealant system and suitable containment dikes;
  - Shelving and storage racks fitted with plastic containment trays;
  - Additional bracing, straps and cushioning of containers in areas of seismic activity
- The mercury waste in the storage facility can be segregated to the following risk categories.
  - Risk level 1 (highest) – elemental mercury, unbroken sphygmomanometers and medical devices containing large amounts of mercury (e.g. gastro-intestinal tubes, esophageal dilators, etc.)
  - Risk level 2 – unbroken mercury thermometers, small switches and relays from electrical equipment
  - Risk level 3 – broken glassware contaminated with mercury, mercury cleanup waste
  - Risk level 4 – fluorescent lamps, compact fluorescent bulbs, dental amalgam
- In facilities which accept other types of hazardous wastes, mercury wastes should not be stored near incompatible chemicals such as acetylene, alkali metals (lithium, sodium), aluminum, amines, ammonia, calcium, fulminic acid, halogens, hydrogen nitric acid with ethanol, oxalic acid and oxidizers.
- The administrative and record-keeping area must be kept separate. Records must be maintained in good order and kept in a secure location.

- Other storage and space design requirements include presence of:
  - Intrusion detection and alarm system;
  - Temperature control system to control temperature and humidity; and
  - Fire suppression and alarm system

Aside from the design requirements, the following general procedures must be considered.

- Establishment of a manifest system (traceability chain), where manifest forms containing the source of the waste, transporter, storage facility, relevant government authority, and other relevant information cited in Table 7 are kept.
- Compliance to licensing and registration requirements. To receive a license, the storage facility may be required to submit an ambient air monitoring plan, proof of liability insurance or guarantee bond, emergency preparedness and emergency response plan, description of waste management practices and other procedural guidelines, personnel training, and overall facility design. The storage facility may be inspected to ensure compliance with building, fire, electrical, and other health and safety codes prior to licensing. The regulatory authority may assign a unique identifier number or code to each storage facility.
- Periodic reporting on safety issues, storage conditions and monitoring data should be submitted to the government authority.
- Establishment of a hazardous waste management plan, which includes procedures for:
  - Receiving waste and internal transport;
  - Waste inspection, re-labeling and repackaging;
  - Supplementary containment and storage;
  - Facility inspection and general cleaning (housekeeping);
  - Spill control and cleanup;
  - Emergency procedures;
  - Worker safety (including hazard identification, hazard mitigation, proper use of PPE, ergonomic techniques for handling waste, and medical surveillance);
  - Reporting and record-keeping; and
  - Health surveillance or medical monitoring.

3.9 TREATMENT AND/OR DISPOSAL

Under the Basel Convention, disposal is defined as "*any operation specified in Annex IV...*". Annex IV contains two sections. Section A lists "*operations which do not lead to the possibility of resource recovery, recycling, reclamation, direct reuse, or alternative uses*" (i.e., D-Operations). Section B lists "*operations which may lead to resource recovery, recycling, reclamation, direct reuse, or alternative uses*" (i.e., R-Operations). The Basel Technical Guidelines suggest permitting operations listed in Table 12 for mercury wastes.

In order to choose among the disposal and recovery options in Table 12, several criteria are needed to be considered (Table 13):

1. Technological considerations. This will be dictated by the type and quantity of mercury waste to be managed and will influence the legal framework and financial costs of management.
2. Legal framework. Issues involving attribution of ownership of the waste and responsibility, licensing procedures, waste acceptance and documentation need to be clearly defined and delineated under law. Transition or transfer of responsibility, if any, is also a matter for consideration, particularly at what point do waste generators remove themselves from any liability for the waste.

Table 12 **List of disposal and recovery operations under the Basel Convention**

Code	Recovery Operations	Code	Disposal Operations
R4	Recycling/ reclamation of metals and metal compounds	D5	Specially-engineered landfill
R5	Recycling/ reclamation of other inorganic materials	D9	Physico-chemical treatment
R7	Recovery of components used for pollution abatement	D12	Permanent storage
R8	Recovery of component from catalysts	D13	Blending or mixing prior to submission to D5, D9, D12, D14 or D15
R12	Exchange of wastes for submission to operations R4, R5, R8 or R13	D14	Repackaging prior to submission to D5, D9, D12, D13 or D15
R13	Accumulation of material intended for operations R4, R5, R8 or R12	D15	Storage pending any of the operations D5, D9, D12, D13 or D14

3. Public health and environmental concerns. The twin concerns on the existing capacity to accurately map out possible environmental impacts and the evaluation of risks posed to human health need to be fully understood.

4. Social and political acceptability. There are salient and pressing issues that accompany disposal/ recovery facilities for hazardous wastes such as public acceptance, site situation near environmentally sensitive areas or indigenous peoples' lands, access to courts for legal redress by facility workers and affected communities, among others. Countries that will embark on establishing disposal facilities need to embrace these issues together with the technological requirements.

5. Financial implications. At the core of this category is the source of funds for the facility, whether it will be a shared enterprise, borne by the waste generator, or subsidized by the government.

3.9.1 Mercury Recovery

Mercury wastes containing mercury or mercury compounds are treated in dedicated facilities to extract and purify the mercury contained in the waste for re-use or disposal operations. Mercury recovery from solid waste comprises of: (1) pre-treatment; (2) thermal treatment; and (3) purification, which should be done in a closed system under reduced pressure to minimize mercury emissions. Any exhausted air emitted in the recovery process must pass through a series of particulate filters and a carbon bed that absorbs the mercury before the air is released to the environment.

Pre-treatment of waste MAPs such as thermometers and sphygmomanometers include dismantling and extraction of mercury without any product breakage to the degree feasible (Figure 8). Then it undergoes vacuum thermal processing, a thermal treatment for thermometers, batteries, especially button cells, dental amalgam, electrical switches and rectifiers, etc. which involves (Figure 9):

1. Heating the input waste in a special kiln or in a charging operation at temperatures of between 340oC and 650oC and pressures of a few millibars;

2. Applying thermal post-treatment to mercury-containing vapor at temperatures ranging from 800oC and 1,000oC where organic components can be destroyed;

3. Collecting and cooling of mercury-containing vapor; and

4. Using distillation to generate pure liquid mercury, which can then be recycle for a use allowed under the Convention.

Table 13 **Criteria for assessing mercury waste disposal and recovery operations based on various guidelines/ sources**

Criteria	Checklist
Technological considerations	1. Characteristics of the mercury waste to be stored (i.e., chemical species, type, concentration/ quantity/ volume) 2. Site-specific requirements: geology, hydrology, frequency of occurrence of natural disasters, location and accessibility, decommissioning and long-term surveillance 3. Storage-specific requirements: chemical-physical criteria for the waste; infrastructure capacity (e.g., building materials); leaching prevention (to control evaporation, erosion, corrosion); monitoring systems; long-term documentation 4. Transportation mode to the facility 5. Use of pretreatment (stabilization and solidification techniques)
Public health, safety and environmental concerns	1. Environmental impacts of facility construction 2. Occurrence of associated risks to human health
Financial implications	1. Capital/ investment costs 2. Operations and maintenance costs 3. Guidelines for financial arrangements (i.e., fee for service)
Social and political acceptability	1. National: presence of legal framework; political stability and stakeholder participation 2. International: presence of bilateral agreements for use and access of storage facility; possible structures for shared responsibility 3. Availability of long-term provisions for sustainability
Availability of human resources	1. Availability of guidelines for salary grades of hazardous waste workers 2. Training capacities on operations, maintenance, and emergency preparedness, among others
Legal/ regulatory framework	1. Presence of legislation such as those concerning import or export restrictions 2. Licensing procedures 3. Waste acceptance rules 4. Documentation and inventory procedures

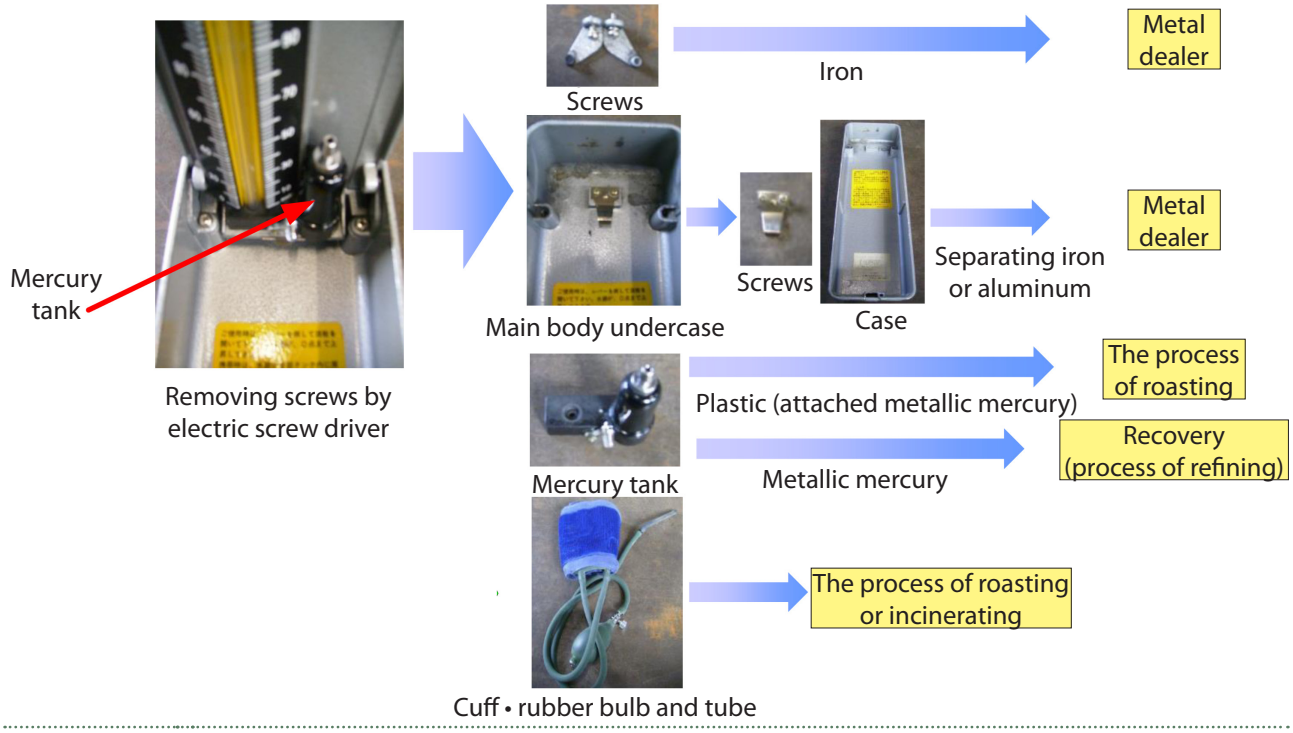
Article 8 of the Minamata Convention calls on Parties to control, and where feasible,reduce emissions of mercury and mercury compounds to the atmosphere through measures that control emissions from point sources falling within the source categories listed in Annex D of the Convention. This includes, among others, waste incineration. Part of the obligations of Parties under this Article is the establishment of emission limit values and the adoption of BAT and BEP (para 6 (b-c)), no later than five years after the date of entry into force of the Convention for that Party (para 4). Meanwhile, Article 9 of the Convention addresses concerns on controlling, and where feasible, reducing releases of mercury and mercury compounds to land and water. Similarly, this requires the establishment of release limit values and the adoption of BAT and BEP to control releases from relevant sources. The implementation plan for release control measures must be submitted to the COP within four years of the date of entry into force of the Convention for that Party (para 4). Detailed guidelines on BAT and BEP for waste incineration facilities are provided in the UNEP (2019) document of BAT and BEP. This includes dust (particulate matter) removal techniques, wet scrubbing techniques, static bed filters, and technologies to treat residues, among others.

In general, to manage residues, emissions and releases from recovery operations, the UNEP and ISWA (2015) sourcebook lists the following steps that need to be undertaken:

- Establish a mass balance, i.e. monitor the amount of mercury entering on one end and captured on the other.

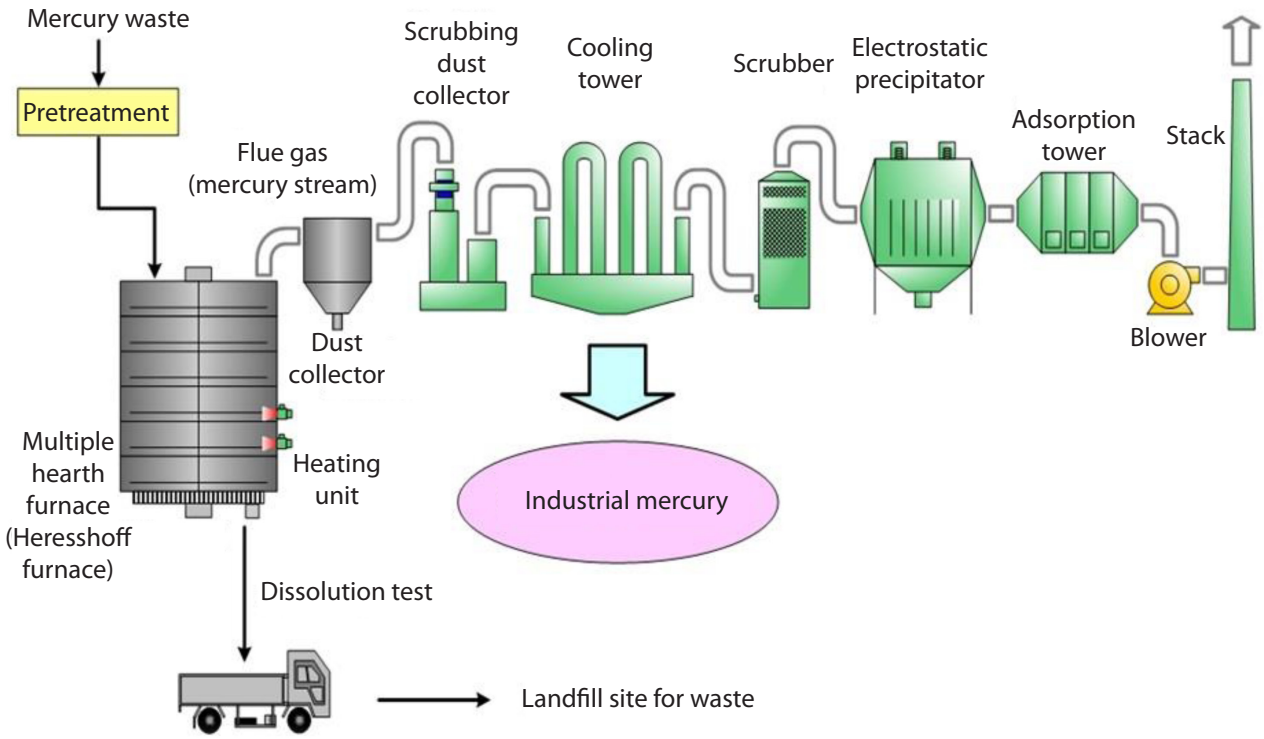
47 Nomura Kohsan. (2021). *Treatment and disposal of mercury waste.* [pptx]
48 Ibid

Figure 8 **Process flow for the dismantling mercury sphygmomanometers at Nomura Kohsan Co., Ltd., Japan[47]**



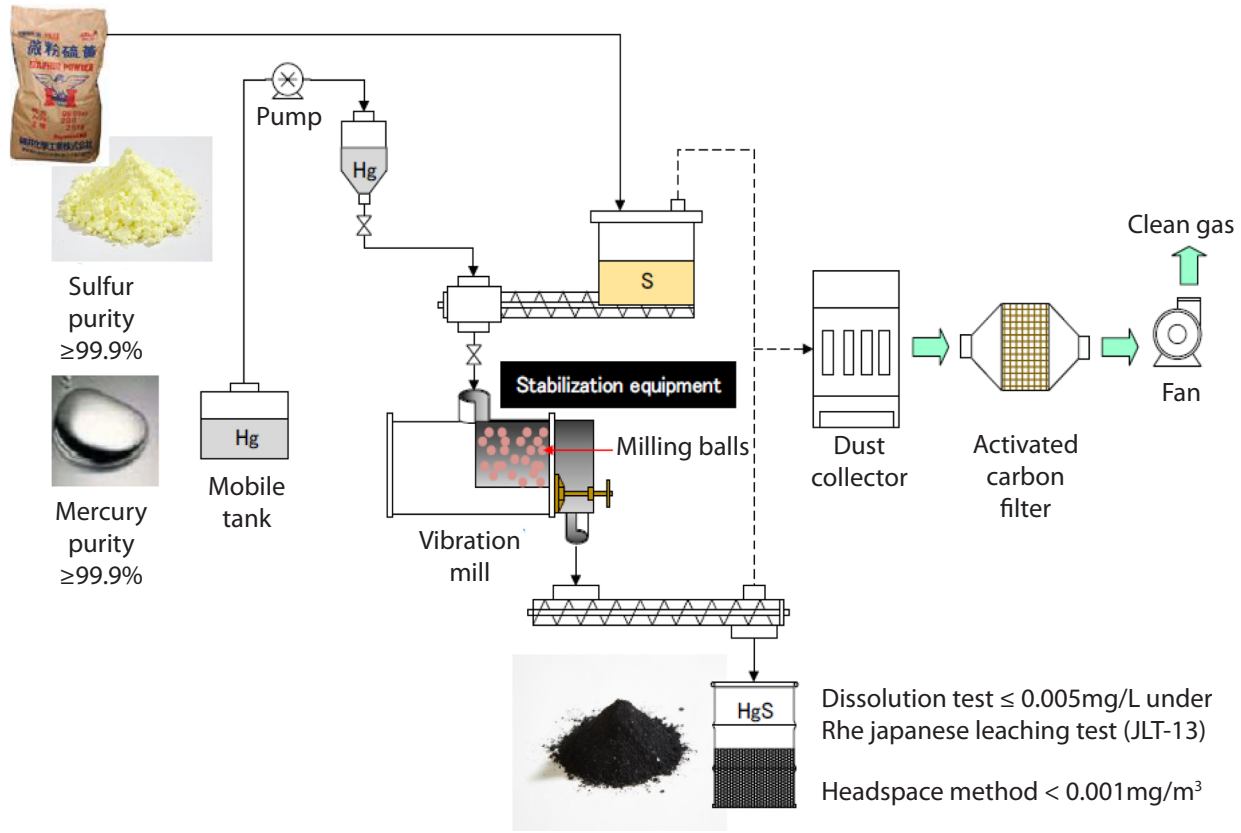
Source: Nomura Kohsan Co. Ltd (2021)

Figure 9 **Process flow for the mercury recovery system at Nomura Kohsan Co., Ltd., Japan**



Source: Nomura Kohsan Co. Ltd 2007, as cited in the Secretariat of the Basel, Rotterdam and Stockholm Conventions, 2015

Figure 10 **Process flow for the stabilization system for mercury at Nomura Kohsan Co., Ltd., Japan[49]**



Source: Nomura Kohsan Co. Ltd 2007, as cited in the Secretariat of the Basel, Rotterdam and Stockholm Conventions, 2015

- Treatment steps during which mercury may be emitted should take place in a closed system under negative pressure to prevent vapour emissions to the atmosphere.
- Mercury in the exhaust air is captured (for example by indirect condensation combined with sulphur impregnated activated carbon filters).
- Mercury in the wastewater is isolated using various physico-chemical treatment steps (for example precipitation, ion exchange).
- Mercury emissions and releases are preferably continuously monitored

However, it is often not possible to extract all mercury contained in the waste. Moreover, a small, but significant portion can be 'lost' during the treatment process. For instance, some mercury can vaporize during pre-treatment, remain in the fly/ bottom ash during thermal treatment, or may contaminate wastewater. Hence, mercury residuals from processing of wastes either undergo further treatment or are disposed in SELs or permanently stored.

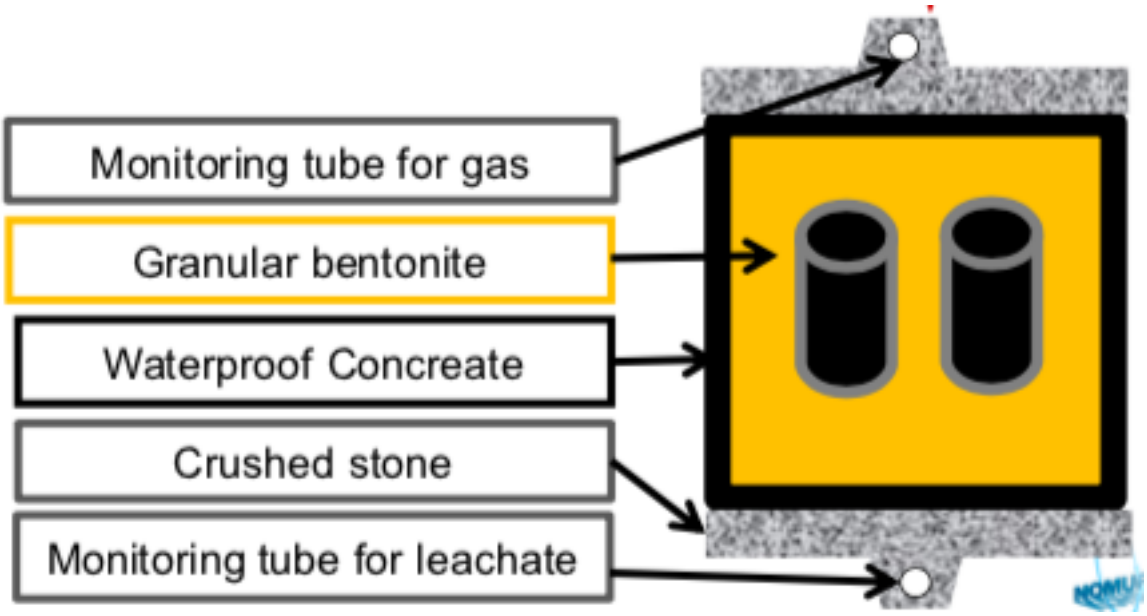
3.9.2 Encapsulation

In cases when the extracted mercury (from MAPs, for examples) is bound for final disposal (e.g., D5 and D12), they should be treated in order to meet the acceptance criteria of disposal facilities. Technologies for the physico-chemical treatment of extracted mercury includes:

1. Stabilization. This include chemical reactions that may change the hazardous characteristics of waste by reducing the mobility and sometimes the toxicity of the waste constituent. One of the most important and

49 Ibid.

Figure 10 **Example of the composition of solidified mercuric sulfide (macroencapsulation) disposed the SEL at Nomura Kohsan Co., Ltd., Japan[50]**



well investigated approaches to stabilization is the conversion of mercury into mercury sulfide (HgS), which is much less soluble and has lower volatility than most mercury compounds and is therefore less mobile in the environment (Figure 10). Mercury is mixed with elemental sulfur or other sulfur-containing substances to form HgS, which can result into two different types: alpha-HgS (cinnabar) and beta-HgS (meta-cinnabar). HgS can also be formed by creating a reaction between mercury and sulfur in a vapor phase.

While HgS is very insoluble in water and has low volatility, exposure to ambient environmental conditions will result in its conversion to other mercury compounds over time. The isolation of HgS from the environment through encapsulation and disposal in a SEL or permanent underground storage may therefore be necessary.

2. Solidification. This includes processes that only change the physical state of the waste (e.g., converting a liquid into a solid) through the use of additives without changing the chemical properties of the waste (Figure 11). Solidification is used to encapsulate or absorb waste and forms a solid material when free liquids other than mercury are present in the waste. Waste can be encapsulated in two ways:

3. Microencapsulation – process of mixing the waste with an encasing material before solidification; or

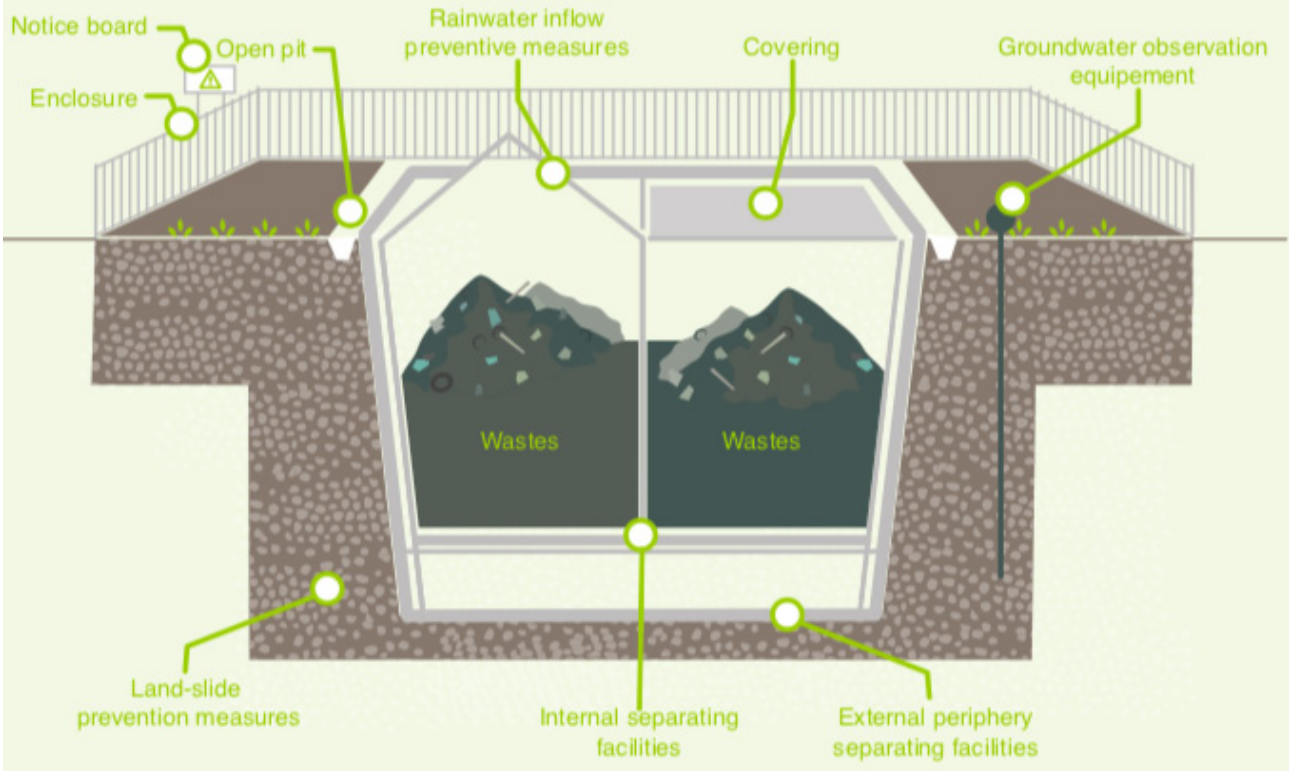
4. Macroencapsulation – process of pouring an encasing material over and around a waste mass, thus enclosing it in a solid block.

5. Solidification of HgS should include materials with low alkali content as a recent study indicates that mercury release from HgS increases when pH value of eluate exceeds 10.

6. Conversion. This includes processes that combine stabilization and solidification and lead to conversion, or the chemical transformation of the physical state of mercury from a liquid state to mercury sulfide or a comparable chemical compound that is equally or more stable and equally or less soluble in water that presents no greater environmental or health hazard than mercury sulfide. The sulfur polymer stabilization and solidification (SPSS) process involves sulfur stabilization followed by solidification, which

50 Ibid.

Figure 10 **A schematic diagram of a SEL[51]**



lowers the change of mercury vaporization and leaching because the final product is monolithic with a low surface area. It involves two steps: (1) stabilization of mercury with sulfur to form meta-cinnabar dust; and (2) microencapsulation of the meta-cinnabar in a polymeric sulfur matrix to obtain a fluid that cools to room temperature and forms solid blocks. The process has low energy consumption, entails low mercury emissions, requires no water, has no effluents and generates no wastes other than HgS. Monolith samples have been tested for leaching and were found to meet the European Union criteria for acceptance of waste into landfills for inert waste (i.e., <0.01 mg/kg).

7. Another example of conversion is the treatment of wastes with sulfur microcements. Application of the technology results in a solid matrix that ensures the confinement of mercury because of its precipitation in the form of very insoluble oxides, hydroxides and sulfides. The process involves mixing of mercury-contaminated waste with the selected sulfur microcement and with water, which is then discharged into the desired mold and matured over a period of 24-48 hours.

8. Another subset of the conversion process is the amalgamation of mercury with other metals such as copper, nickel, zinc and tin, resulting in a solid, non-volatile product. Two generic processes are used for amalgamating mercury in waste: (1) aqueous process and non-aqueous process. However, the mercury in the resulting amalgam is susceptible to volatilization and leaching, as such, amalgamation is typically used in combination with an encapsulation technology.

9. A number of S/S processes have undergone laboratory testing at small and large scale. Prior to using a new technology, there should be careful review of pilot or commercial operational test data for performance and quality assurance/ quality control to assure that treated wastes meet national or international criteria. It is suggested to evaluate physico-chemical treatment methods

51 Ibid. 14

Case Study 6 **SEL in Japan**

The SEL at Nomura Kohsan Co., Ltd., in Japan has a double water structure and is made of reinforced concrete. Only residues below the acceptance standard (i.e., Japanese leaching test < 0.005 mg/L are accepted.

in pilot-scale tests before commercial use, including the:

10. Quality of the stabilization process by determining the conversion rate and the mercury vapour release from the stabilized waste;

11. Leaching potential over a range of plausible disposal conditions (especially over a range of pH values); and

12. Plausible changes to the treated waste in the long-term due to exposure to the environment and biological activity at disposal sites.[52]

3.9.3 Disposal

Once the waste has undergone S/S, final disposal can be done in three ways:

1. **Specially engineered landfills**. SELs are an environmentally sound system for solid waste disposal and is a site where solid wastes are capped and isolated from each other and from the environment. The waste is stored aboveground or near the surface below ground (Figure 12).

   Prior to disposal, the waste (e.g., mercury extracted from MAPs) must undergo stabilization and solidification to ensure compliance with applicable national and local regulations. Table 14 outlines the eligibility criteria currently in use in SELs in EU, the US and Japan:

   In addition, specific requirements pertaining to site location, design and construction, landfill operations and monitoring should be met to prevent leakages and contamination of the environment:

Table 14 **Eligibility criteria for SELs[52]**

EU	US	Japan
Only wastes with leaching limit values of 0.2 and 2 mg Hg/kg dry substance at a liquid-solid ratio of 10 L/Kg in landfills for non-hazardous and hazardous wastes respectively.86 Some EU member states prohibit aboveground landfill disposal of waste with a mercury content above a certain limit value (e.g. Netherlands, Sweden, Belgium).	Only low concentration mercury wastes can be treated and landfilled; treated mercury wastes must leach less than 0.025 mg/L mercury (by TCLP testing).	Treated wastes with mercury concentration equal to or less than 0.005 mg/L accepted in landfills for domestic and industrial wastes (leachate-controlled type); wastes with mercury concentration in excess of 0.005mg/L disposed at landfills for hazardous industrial wastes (isolated type)

52 Ibid. 10

- **Duration.** In theory and for a defined time period, a landfill site can be engineered to be environmentally safe subject to the site being appropriate and with proper precautions and efficient management.

- **Site selection**. Sites with favourable natural and artificial containment properties are ideal. Decision for site selection should be further based on evaluation of detailed technical, biological, social, economic, and environmental factors. These include:

  - Geographical, geological and hydrogeological properties of the site, including the possibility of ground water pollution
  - Future use of the landfill area
  - Degree of urbanization and its proximity to the site[53]

- **Safety requirements.** To minimize risks to human health and the environment, it is suggested to ensure that preparation, management and control of the landfill as well as the process of site selection, design and construction, operation and monitoring, closure and post closure care are of the highest standard. The site needs to be specially engineered for the purpose of disposal of mercury wastes. Overall engineering should ensure isolation from the environment that is as complete as possible. Key requirements to prevent leakages and contamination of the environment include, among others:

  - Establish a permit system, stipulating leachate and gas control systems, closure and post-closure measures etc.
  - Conduct of thorough environmental impact assessments and analysis of the long-term behavior of stabilized mercury wastes in the specific settings of the facility
  - Disposal of the waste in dedicated cells, separate from other wastes
  - Establishment of control and oversight procedures are; periodic monitoring and

Case Study 7 **Permanent storage in underground salt mines in Germany.**

Placement of bags and drum containers in the Herfra Neurode salt mine[53]

The underground landfill in Herfa Neurode, Germany is an example of a permanent underground storage for mercury. It is composed of both natural (salt, clay and bunter stone) and artificial (brick walls, field dams, watertight shaft sealing) barriers, with depths reaching 800 m or below the ground water. The waste is stored in disused, excavated areas of the mine, with frequent monitoring of mercury vapor being done.

53 Ibid. 14

evaluation of leachate and off-gassing is undertaken

- Installation of bottom (operating phase) and top-liner (closure and post-closure phase)

2. **Permanent storage in underground facilities**. After having been solidified or stabilized, mercury wastes (that meet the acceptance criteria) maybe permanently stored in special containers in designated areas in underground storage facilities. The intent is to permanently isolate mercury wastes from the biosphere by including it as completely and permanently as possible in a suitable host rock via several natural and artificial barriers.

   Potential sites could be underground mines that are no longer used and have suitable geological conditions, once they have been specifically adapted for the purpose. Potential host rocks include the following:

   - **Salt rock**. Salt rock is considered impermeable to liquids and gases and a very effective barrier for longterm storage of hazardous waste. A minimum thickness of the salt layer, however is needed to ensure safe encapsulation. Few countries have suitable formations.

   - **Clay formations**. Also considered as very good barrier. Although not impermeable, migration of pollutants is considered to be extremely slow. Many deposits can be found worldwide.

   - **Hard rock formations**. Although typically fractured, may provide sufficient long-term safety if combined with technical barriers. This type may be found in many regions worldwide.

     Other rock formations can be suitable as long as the overall geological situation can ensure long-term isolation of the hazardous substances. All potential sites have to be carefully assessed and additional technical barriers must be in place. As discussed in Table 14, the choice of a site is governed by a number of factors, including geological conditions, permitting procedures, construction, operation, financial considerations and the prospects of gaining local consent. Other factors that need to be considered include the:

     - layout of storage facilities;
     - types of containments used;
     - storage location and conditions;
     - monitoring;
     - site access conditions;
     - storage closure strategy;
     - sealing and backfilling, and
     - depth of storage.

3.10 EXPORT

The export of mercury waste for final disposal is a critical option for countries that do not have necessary infrastructure for its environmentally sound management. It may also be the preferred choice for countries with relatively small amounts of mercury waste, where the cost-benefit analysis shows that the establishment of domestic infrastructure is not financially sustainable. Some countries may see export as an interim solution, until domestic facilities become available.

1. Where applicable, all shipments should be made in accordance with the Minamata Convention (Article 11 para 3 (c)):

"Each Party shall take appropriate measures so that mercury waste is...

(c) For Parties to the Basel Convention, not transported across international boundaries except for the purpose of environmentally sound disposal in conformity with this Article and with that Convention. In circumstances where the Basel Convention does not apply to transport across international boundaries, a Party shall allow such transport only after taking into account relevant international rules, standards, and guidelines."

2. as well as the Basel Convention (Article 9):

"Parties shall take the appropriate measures to ensure that the transboundary movement of hazardous wastes and other wastes only be allowed if:

(a)The State of export does not have the technical capacity and the necessary facilities, capacity or suitable disposal sites in order to dispose of the wastes in question in an environmentally sound manner; or

(b)The wastes in question are required as a raw material for recycling or recovery industries in the State of import; or

(c) The transboundary movement in question is in accordance with other criteria to be decided by the Parties, provided those criteria do not differ from the objective of this Convention."

Furthermore, Articles 6 of the Basel Convention specifies how transboundary movement between Parties will be conducted, while Article 9 enumerates the transboundary movements that can be considered as "illegal traffic" under the Convention:

1. All notifications and responses shall be coursed through the competent authority of the relevant State.

2. The State of export shall notify in writing the all concerned States of any transboundary movement of mercury waste. This includes the declarations and information specified in Annex V A of the Convention.

3. The State of import shall respond in writing consenting or denying permission of or requesting additional information on the movement.

4. Transboundary movement will commence if:

   - The notifier has received the written consent of the State of import; AND
   - The notifier has received from the State of import confirmation of the existence of contract between the exporter and the disposal facility specifying the ESM of the waste in question.

5. Each State of transit which is a Party shall promptly acknowledge the notifier receipt of notification, and may respond in writing, within 60 days. The State of export shall not proceed allow the movement until receipt of the written consent from the State/s of transit.

Whether export might be a cheaper solution than the alternatives depends on a number of factors, e.g. the volume of mercury wastes. According to the proceedings of the experts meeting organized by UNIDO (2018), a domestic treatment facility is only feasible if there is more than 1,000 tons of waste being managed per year, otherwise, alternatives for local treatment is needed. It is difficult to give general cost estimates, as they vary greatly (e.g., due to energy prices). Main cost factors include insurance, packaging, customs, freight and shipment fees, and the costs or treatment/ storage/disposal in the country of destination. In addition, important ESM export steps include the following:

Table 15 **Service providers that can treat MCMMDs**

Name of Company	Location	Description of Services
BATREC Industrie AG	Wimmis, Switzerland	Extracted mercury from thermometers will be: 1. Stabilized as HgS for permanent storage in Germany 2. Recovered with a purity >99.99% for recycling in accordance with the Minamata Convention They can organize and supervise transport of the waste from all over the world.
Ecocycle Pty Ltd	Victoria, Australia	Distillation of mercury for recycling
Ecologic SA	Panama City, Panama	Final disposal via concrete encapsulation Long-term storage of mercury and mercury compounds for future processing
Nomura Kohsan Co, Ltd	Tokyo, Japan (head office)	Production of HgS using mechanochemical reaction, which is then disposed in a leachate-controlled SEL
Remondis QR	Dosten, Germany	Accepts metallic mercury for stabilization to HgsS, which is sent to German salt mines for long-term storage

- Seek regional solutions in order to avoid unnecessary risks associated with transportation of mercury wastes;
- Address issues of ownership, liability and traceability; and
- Ensure that the rules and procedures of the Minamata and Basel Conventions and/or relevant international rules, standards and guidelines are observed.

Written documents required to facilitate transboundary movement include:

- notification for all concerned countries (import, export, transit), which will include the declarations and information requested in the Convention
- prior written consent from all concerned countries (import, export, transit)
- insurance, bonds or guarantees
- confirmation of the existence of a contract specifying ESM of the wastes between exported and the owner of the disposal facilities

For Parties opting to export their wastes for ESM, the UNEP Global Mercury Partnership developed a Catalogue of Technologies and Services on Mercury Waste Management that can be considered. Out of the 10 services providers identified, the following were found capable to treat MCMMDs:

3.11 MONITORING

Throughout the logistics chain, it is important to establish the traceability of mercury wastes to ensure that they are not diverted for illegitimate uses or are inadequately disposed. Traceability is an approach which identifies and records every activity of hazardous waste management—from generation to disposal. Existing guidelines note that traceability applies to relevant parties upstream (e.g., waste generators) and downstream (e.g., transporters, recyclers, disposers). When a comprehensive traceability approach is implemented, important information on the characteristics, concentration, and quantity of the waste as well as the risks associated with its management are available to the relevant local and/or national authorities at all times. Specifically, this information will allow authorities to audit/ inspect the traceability chain and enforce liability to the different holders of the waste. Moreover, each person/ entity involved

Figure 13 **Traceability chain**[54]

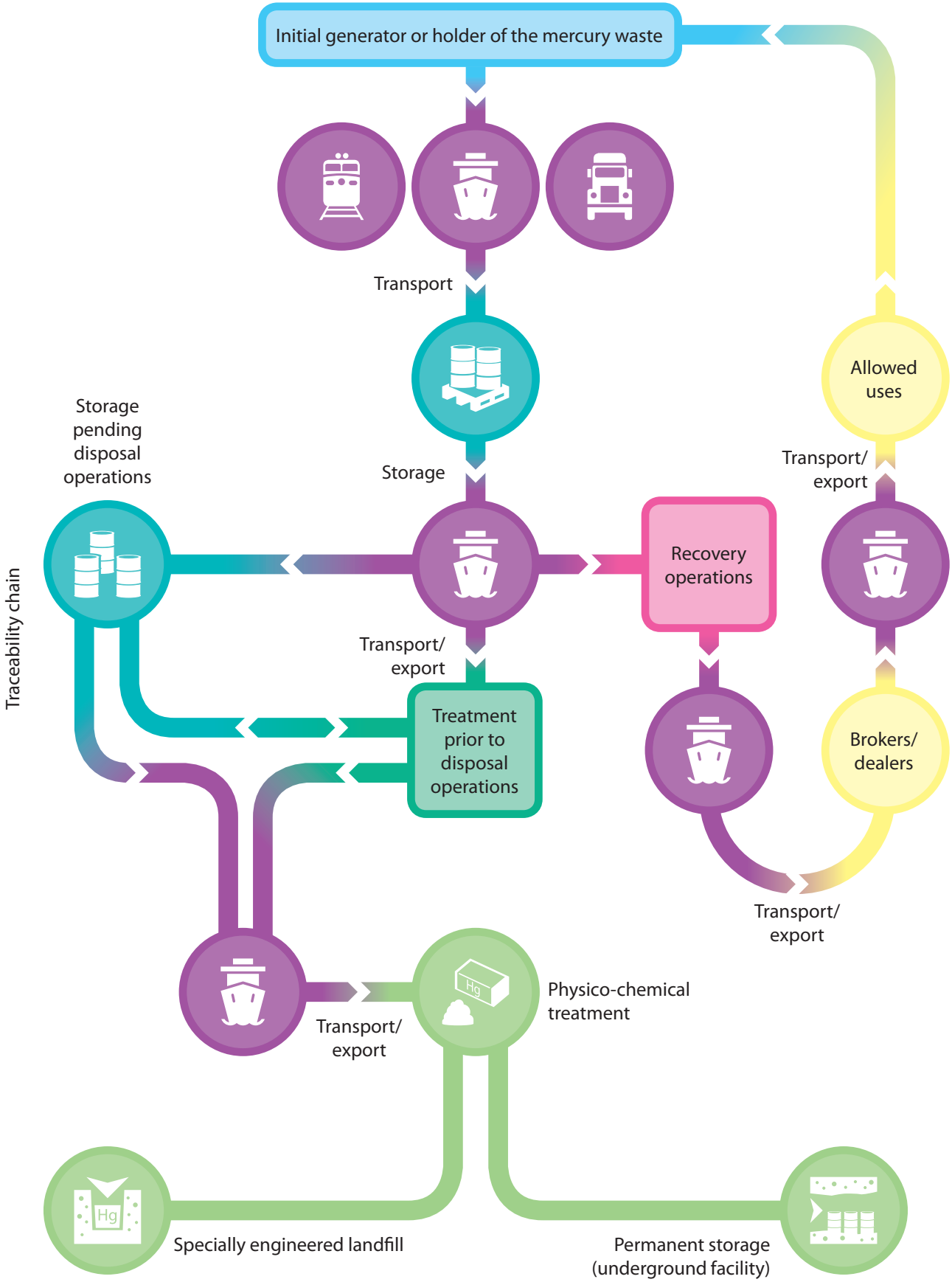


Table 16 **Required mercury waste information along the traceability chain**

At the entrance of each delivery	At the exit, for each shipment departure
▪ Identification of the shipment (including notification ID in case of export) ▪ Source of mercury waste (including registration number of waste generator) ▪ Date of delivery ▪ Person in charge of the transport (contact details and signatures) ▪ Person in charge of the transfer (import/export) (contact details and signatures) ▪ Previous holder and origin ▪ Description of waste (with relevant identification code, if applicable) ▪ Quantity of the mercury waste (number of containers, weights, approximate volumes) and descriptions of the waste (including composition and information on how the mercury waste was generated) ▪ Any notes or observations on the condition of the waste when received and any corrective actions taken (e.g., repackaging or re-labeling) ▪ Special handling procedures or warnings if appropriate ▪ Location of the storage in the facility	▪ Identification of the shipment (including notification ID in case of export) ▪ Source of mercury waste (including registration number of waste generator) ▪ Date of departure ▪ Person in charge of the transport (contact details and signatures) ▪ Person in charge of the transfer (import/export) (contact details and signatures) ▪ Next holder and description of the destination/purpose ▪ Description of waste (with relevant identification code, if applicable) ▪ Quantity of the mercury waste (number of containers, weights, approximate volumes) and descriptions of the waste (including composition and information on how the mercury waste was generated) ▪ List of the ID of all the flasks for waste mercury/recovered from the waste ▪ Any notes or observations on the condition of the waste when received and any corrective actions taken (e.g., repackaging or re-labeling) ▪ Special handling procedures or warnings if appropriate ▪ Records of accidents, spills, worker injuries and chemical exposure ▪ Estimated date of arrival at the destination

in the traceability chain will be able to provide a mass balance of the mercury wastes held, taking into account emissions/ losses.

A traceability chain is summarized in Figure 13. UNEP and ISWA (2015) notes that each person/ entity involved in the ESM of mercury wastes should report the information presented in Table 16 in the tracking records.[54]

3.12 FINANCING

The Minamata Convention recognizes the need to provide financial assistance, especially for developing nations, to improve the implementation of the provisions set by the different Articles. Hence, Article 13 establishes a financial mechanism with two components:

- The Global Environment Facility (GEF) Trust Fund; and
- A Specific International Programme (SIP) to support capacity- building and technical assistance.

While financial assistance will be made available, the Convention calls on Parties to provide, within its capabilities resources for national activities that are intended to implement its obligations. Such domestic funding can be sourced through relevant policies, development strategies and national budgets, as costs borne by the private sector (para 1). In addition, the Convention encourages the establishment of multilateral, regional and bilateral sources of financial and technical assistance to enhance and increase activities of developing nations toward the implementation of the Convention (para 3).

3.13 STAKEHOLDERS INVOLVED

Governments and responsible authorities have a leading role to play in the implementation of ESM by setting requirements in their legislation and by

54 Ibid. 14

implementing and enforcing them. In particular, they should:

- Ensure that a national policy, supported by an appropriately resourced and integrated regulatory and enforcement infrastructure, at an appropriate government level;
- Foster continual improvement within the waste management sector;
- Provide incentives to foster the development of infrastructure for relevant waste management technologies and facilities that support the leading elements of the waste management hierarchy and EMS;
- Put in place measures to ensure due diligence and proper management of wastes by all operators downstream of the point of generation;
- Be transparent and require transparency to the public, within the bounds of business confidentiality principles;
- Establish effective consultation mechanisms or partnerships with key stakeholders;
- Ensure adequate investment in waste management infrastructure and ESM of wastes at the national level;

Other stakeholders involved in waste management also have an important role to play. In particular, the ESM Framework notes that:

1. Waste generators are responsible for integrating BAT and BEP when undertaking activities that generate wastes. This means that they should internalize waste prevention and minimization measures within their operations and ensure that any hazardous waste generated will be managed in an environmentally sound manner whether treatment/ disposal is done internally or by a third-party.

2. Waste carriers should have a license/ permit to carry out the transport of wastes, ensuring that these are adequately packed, handled, and documented properly. Adequate measures must also be in place to prevent harm to human health and the environment while the wastes are in their possession and/or under their control.

3. Waste dealers and brokers should have a license/ permit to buy and sell wastes, ensuring that trade is conducted in compliance with national requirements and international law, and that the waste in their possession are managed in an environmentally sound manner.

4. Waste management facilities should, at the minimum, meet all basic requirements to ensure ESM of wastes. They should also commit to continual improvement in their operations, evolving as new BAT and BEP are established. The whole life cycle of the facility should be covered, from planning and construction to subsequent dismantling or site remediation.

Non-governmental organizations can serve as independent monitors and sources of research and information, policy development, public education and awareness-raising.

3.14 PUBLIC AND WORKERS' SAFETY

The ESM of mercury and mercury waste requires the development and implementation of public and worker health and safety activities to prevent and minimize exposure. Specifically, Article 16 of the Minamata Convention encourages Parties to promote the development and implementation of strategies and programs to protect and identify vulnerable populations, promote science-based educational programs, promote, healthcare services for mercury treatment and exposure prevention, among others.

1. Public health and safety. Public health activities may include programs which prevent and minimize exposure by establishing mercury limitations from commercial and industrial sources which may emit, discharge or dispose mercury or mercury wastes into the environment. These activities may also include approaches to reduce exposure from the breakage of mercury thermometers and

Table 17 **8-hour TWA values for mercury and mercury compounds[55]**

Source	Year	Values (µg/m3)
EU	2009	20
Austria	2003	50
Bulgaria	2007	25
Czech Republic	2004	50
France	2006	50
Germany	2007	100
Hungary		80
Italy	2009	20
Netherlands	2007	50
Norway	2009	20
Poland	2009	20
Portugal		25
Romania	2006	50
Slovakia		100
Slovenia	2001	100
Spain		25
Sweden		30
Switzerland	2007	50 (inhalable aerosol)
United Kingdom		25
Russia	2009	5
US	1994	25

implement rapid clean-up of such spills. Public health and safety programs may also wish to pay particular attention to protecting populations that are more sensitive to the effects of mercury wastes, including fetus, newborns and children as well as new mothers and pregnant women.

2. Worker health and safety. Worker health and safety programs may consider activities which assure that workers who collect, transport, store, and dispose mercury wastes are adequately trained and are provided equipment which prevents or minimizes them from exposure to mercury wastes. Worker health and safety measures include:

55 Euro Chlor. (2010). Code of Practice for the control of worker exposure in the Chlor Alkali industry. [online]. Retrieved 22 May 2021 from: https://wedocs.unep.org/bitstream/handle/20.500.11822/13103/Health_2_Edition_6.pdf?sequence=1&isAllowed=y

Table 18 **15-minute STEL values for mercury and mercury compounds[56]**

Source	Year	Values (µg/m3)
Austria	2003	500
Czech Republic	2007	150
Germany	2007	800
Hungary	2007	320
Italy	2009	25
Netherlands	2007	500
Romania	2006	150
Slovakia		800
Switzerland	2007	400 (inhalable aerosol)
Russia	2009	10

- Provision of employee training in effective ESM
- Use respirators with mercury filters and personal protective clothing
- Take urine samples from workers on a continuous basis
- A regular intake of selenium may protect against mercury exposure
- Health, safety and emergency plans in place based on risk assessment
- The principal elements of an emergency plan include identification of potential hazards, actions to be taken in emergency situations, communication targets and methods in case of emergency, and testing of emergency response equipment

In addition, ambient air mercury monitoring may be conducted in facilities to ensure that workers' exposure do not exceed the national legal occupational exposure limit. Current occupational exposure limits in other countries are found in Table 17:

Aside from the 8-hour TWA, some countries also proposed short-term exposure limits (STEL) (Table 18).

56 Ibid.

PHILIPPINE GUIDELINES FOR THE ENVIRONMENTALLY SOUND MANAGEMENT OF MERCURY-CONTAINING MEDICAL MEASURING DEVICES

4.1 WASTE PREVENTION AND MINIMIZATION

The existing Philippine policy framework puts a great emphasis on waste prevention and minimization as the priority strategy for the ESM of chemicals and hazardous waste. Even before the ratification of the Minamata Convention, the country has long-standing provisions prohibiting the manufacture, import, use and export of MCMMDs, such as the DOH AO 2008-21, which established the phaseout of MCMMDs in healthcare facilities in the Philippines. Specifically, the AO ordered the immediate discontinuation of the distribution of mercury thermometers to patients, and the development and implementation of mercury minimization programs in healthcare facilities within two years from the effectivity of the order. Meanwhile, the updated CCO on mercury specified the phaseout schedule for such MAPs, indicating that MCMMDs will be considered as mercury wastes intended to be disposed of in an environmentally sound manner by 2022. Before the phaseout schedule, any person or entity importing, manufacturing, distributing, storing or is an allowed user of MAPs are required to register with the DENR-EMB and secure clearance from the CDRRHR before they can import, manufacture, distribute, store or use MCMMDs. However, this transition period will narrow down as the FDA plans to issue the draft circular banning MCMMDs in the Philippines within the year.

The mercury minimization program espoused in DOH AO 2008-21 covers the development and implementation of a purchasing policy that requires vendors to sign a mercury-content disclosure agreement covering products intended for purchase. The AO noted that there should be preference for mercury-free alternatives, and that effort should be made for suppliers and staff to facilitate the switch. In this light, the CDRRHR technical specifications for thermometers, a regulated medical device, reflected the transition to mercury-free alternatives.

Health facilities that continue to purchase/ use/ dispose MCMMDs are considered as waste generators. Waste generators are facilities which produce hazardous wastes that are specified by the EMB. As per DAO 2013-22, waste generators are responsible for these wastes from the time these are created until certified as non-hazardous by an EMB-registered TSD facility. EMB breaks down waste generators into 3 categories based on the number of types of wastes it generates and the quantity of these wastes. Facilities producing mercury and mercury compounds as wastes are categorized as small generators if they produce less than 10,000 kg per year of this waste, medium generator if they produce between 10,000 kg to 20,000 kg per year, and large if they produce more

than 20,000 kg per year. Regardless of the volume of waste produced however, a facility which creates more than 1 type of waste is immediately classified as a large generator.

Aside from registering online, waste generators must also fulfill the following requirements:

1. Designate a full-time PCO;
2. Disclose the type and quantity of waste generated, submit all the required documentary requirements, and pay the prescribed fees;
3. Submit a Self-Monitoring Report (SMR), which shall include the type and quantity of waste generated and transported offsite for treatment or storage;
4. Complying to the hazardous waste wtorage and transport Requirements;
5. Adhere to the hazardous waste transport manifest system;
6. Prepare and submit comprehensive emergency preparedness and response program to mitigate spills and accidents involving chemicals and hazardous wastes;
7. Communicate to its employees the hazards posed by the improper management of mercury wastes; and
8. Develop capability to implement the emergency preparedness and response programs and continually train core personnel on the effective implementation of such programs.

Regardless of waste generator category, the requirements and process for the storage, treatment, and disposal of MCMMDs are the same. The only differences are in the frequency of reporting to EMB and the storage time limit of hazardous wastes (Table 19):

Table 19 **Report and storage requirements of waste generators**

Category	SMR Submission	Storage Time Limit
Large Generator	Quarterly	6 months
Medium Generator	Semi-annual	1 year
Small Generator	Annual	1 year

4.2 ON-SITE ASSESSMENT AND INVENTORY

Due to their phaseout in the healthcare setting, MCMMDs are considered as hazardous wastes in the Philippines, with its disposal falling under the purview of the DENR EMB. Based on DAO 2013-22, these devices are classified under category D407 or *mercury and mercury compounds*, and are defined as containing mercury concentration of more than 0.1 mg/L.

To further support the management of mercury and mercury wastes in the country, the DENR has embarked on an assessment of mercury using the UNEP Toolkit in 2008. It estimated the total mercury from thermometers using the bed capacity of hospitals in the Philippines and the default input factor in the Toolkit. Results of the computation found a total of 198 kgs of mercury that are emitted per year from thermometers. No estimates were given for sphygmomanometers. Meanwhile, the 2019 Minamata Initial Assessment using the UNEP Level 2 Toolkit lumped mercury emissions from thermometers together with other consumer products with intentional uses of mercury. The report identified 1,675.8 kgs of mercury generated from this source category per year.

There are several policies that can theoretically provide information on the inventory of MCMMDs (Table 20). However, these need to be verified further. For instance, centralized data on the mercury audits conducted following DOH AO 21-2008 are not available, whereas the manifest system established through DAO 2013-22 aggregates mercury wastes under one category.

Table 20 **Potential sources of inventory data**

Policy	Description
DOH AO 2008-21	The AO required healthcare facilities to conduct a mercury audit, collecting information on the sources of mercury in the facility, as well as the safety, purchasing and disposal practices of facilities
DENR AO 2013-22	As waste generators, healthcare facilities must register and disclose to the DENR the type and quantity of waste they have generated, which includes waste MCMMDs. This will be further documented in the manifest system.

4.3 PACKAGING

According to DOH AO 2008-21, mercury-containing products must be stored in non-breakable containers with tightfitting lids. However, further guidance on packaging MCMMDs are not available. Packaging requirements based on DAO 2013-22 are as follows:

- Each vessel or container contains only mercury and mercury compounds.
- Vessels or containers are tightly sealed;
- Used vessel or container is cleaned before being reused;
- Multiple wastes are packed separately according to type and composition;
- Mercury and mercury compounds in small can be packed in a larger over pack container. Each individual container is labelled with its contents and properly sealed. Compatible absorbents can be used and placed in the bottom of the over pack container.

4.4 LABELLING

Proper labeling should also be done at the waste generator's facility and should be maintained up to the TSD facility. Below are the labeling requirements according to DAO 2013-22:

- Minimum size of the label is 20cm - 30cm or readable five meters away;
- Color of the label is yellow for background and black for letters conspicuously marked in paint or other permanent form of marking;
- Material of the label should be scratch-proof and resistant to tampering and weathering;
- Basic form as provided below

HAZARDOUS WASTE		
Waste Information	HW Class and No.	Mercury and mercury compounds / No. D407
	Characteristic & form	Toxic
	Volume	Volume of the waste contained in the vessel or container
	Packaging date	Date on which the waste is packed in the vessel or container
	Shipping date	Date on which the waste must be removed from the storage area and transported offsite if applicable
	Waste transport record number	Manifest number if transported offsite

Generator Information	ID number	ID number issued by DENR upon registration
	Name	Name of the waste generator (company name)
	Address	Address of the waste generator
	Telephone #	Telephone number of the waste generator
	Fax #	Fax number of the waste generator
	Name of HWMS or PCO	Name of hazardous waste management supervisor (HWMS) or the PCO

- Label is accompanied by a placard corresponding to the characteristics of mercury and mercury compounds contained in the vessel or container. It must follow the specifications and placement below
  - Placard design

  - Minimum size of the placard is 10cm x 10cm for vessels or readable from five (5) meters afar
  - For waste transporting vehicles, readable from ten (10) meters afar and a minimum size of 30cm x 30cm
  - Basic shape of the placard is a square rotated 45 degrees to form a diamond
  - At each of the four sides, a parallel line shall be drawn to form an inner diamond 95% of the outer diamond
  - Color should follow the colors specified in the placard design shown above
  - The placard shall be attached to the side of the vessel. If the vessel is used repeatedly, the placard can be a plate and hung on the side of the vessel that stores the wastes.
  - Conveyances transporting wastes shall place the corresponding placards at all sides of the waste transporting vehicles.

In case of export, additional label as required by international standard should be attached.

4.5 TEMPORARY STORAGE AT HEALTHCARE FACILITIES

DOH AO 2008-21 provided some guidelines for setting up interim storage areas within healthcare facilities. These include:

- The storage area must be clearly delineated by fencing, posts or walls to limit access to site. Adequate security sitting and access to area should be observed;
- A recording system shall be established, including information on the name of inspector, date of inspection, dates when mercury and MAPs are placed/ stored;
- The area must have adequate roof and walls to protect wastes from rainwater;
- There should be no cracks or openings in the containment floor or walls;
- The floor should be constructed of impervious materials (e.g., concrete, steel), or if mercury is in liquid form, be surrounded by a bund wall to contain spills;
- Visible warning signs and notices must be present;

- Drainage facilities shall be installed;
- Emergency showers and eyewash units with adequate water supply should be made available at all times;
- Firefighting equipment must be present;
- Only authorized personnel with adequate training should have access to the area;
- A copy of the MSDS shall be available;
- Segregation and adequate ventilation should be maintained;
- A workable emergency plan must be implemented in cases of spillage and emergencies; and
- Only trained personnel should be in-charge of transporting the wastes.

4.6 OFF-SITE TRANSPORTATION

Prior to transport, DAO 2013-22 notes that a pre-transport inspection and packaging and labeling check be done. Hazardous waste transporters must register to the DENR EMB and provide the following requirements:

- Business Permit and SEC Registration Certificate
- Description and Specification of Conveyance, Details of Transport Service
- Photographs of conveyance (inside and outside parts of vehicle)
- Proof of ownership of the vehicle (Official Receipt and Certificate of Registration)
- Registration from Land Transportation Office, including the result of air emission testing
- Provision of an appropriate facility that will be used as garage for the vehicles (include sketch map and photographs)
- Certification from the Department of Transportation and Communication (DOTC) signifying that the vehicles are fit to transport hazardous materials
- Name of Drivers and other personnel including proof of competency:
  - Certified true copies of Professional Driver's License, indicating that the proposed drivers have the appropriate licenses to drive the vehicles for waste transport
  - Certificate of Training from duly recognized trainings on waste management md emergency preparedness and response. The training certificate must have been issued within the last three years. The training shall cover the following topics and must be at the minimum of eight hours:
    - Waste identification and classification
    - Hazard Categorization and Operability
    - Separation and segregation
    - Placards and Label
    - Personal Protective Equipment
    - Safety Data Sheet
    - Emergency and Contingency Planning
    - Applicable Government Regulations
  - Contingency and Emergency Plan based on Risk Assessment Studies
  - Environmental Guarantee Fund in the form of commercial insurance, surety bond, trust fund, or a combination thereof, whose amount is commensurate to the identified risks (from the Risk Assessment Studies) and callable upon demand by the Department during spill or emergency
  - Valid contract with a registered TSD facility/ies.

For the transport vehicles to be used, the following requirements need to be complied with:

- Be strong enough to carry the load without difficulty
- Be in good mechanical condition
- Have sealed flooring in the cargo compartment(s)
- Must have grounding systems particularly if it transports ignitable substances and wastes
- Not have any exposed spark producing metal inside, which could come in contact with wastes that have explosive properties
- Be examined for abrasion, racking or dents, corrosion, and weld defects in the following:
    - Braking equipment
    - Tank pressurization tests
    - Piping
    - Valves
    - Gaskets
    - Fittings
    - Bolts
    - Nuts
    - Closures
    - Fastening systems
    - Pressure relief devices
    - Thermal protection systems
- Waste transport vehicles shall have all required markings on each side and each end of the vehicle. These markings must be correct, legible, and readable up to ten meters from the vehicle. The following are the minimum markings:
- Name and Transporter Registration ID Number of the waste transporter
- Warning signs corresponding to the wastes being transported

Meanwhile, the following procedures must be followed to minimize risks during transit:

To minimize the risks while on transit, waste transporters must follow the procedures below that are set by the EMB:

- Ensure that its duly authorized driver keeps the following in the vehicle at all times during transport:
    - Printed and duly signed Hazardous Waste Manifest Acknowledgement Letter from EMB Regional Office
    - Emergency response plan specific to the wastes being transported
    - Emergency response equipment such as pigs, booms, fire extinguishers, oversized drums for holding defective drums, personal protective equipment (PPEs), etc.
    - Communication equipment
- Approved route from waste generator to TSU facility clearly indicating the plan to avoid densely populated areas, watershed or catchments areas, and other environmentally sensitive areas
    - Provide adequate number of helper or aids in addition to the driver during transport of hazardous wastes. These helpers or aids shall also have the appropriate training in hazardous waste management
    - Receive wastes that are properly packaged and labelled and transport the entire quantity to the TSD facility indicated in the Hazardous Waste Manifest Acknowledgement Letter
    - Ensure that its transport vehicles have warning signs, markings, and other

requirements by the DOTC on transporting hazardous materials

- Attach placards on the conveyances as specified in the DAO 2013-22
- Immediately inform the waste generator (who shall in turn inform EMB Regional Office) in extreme case where wastes cannot be delivered to the destination indicated on the manifest form. The waste generator shall instruct the waste transporter to return the wastes to the waste generator
- Ensure that wastes of different subcategory or different waste generator should not be mixed during transport, trans-shipment, and storage
- Immediately notify the EMB Regional Office(s) having jurisdiction over the waste generator or waste transporter, the DOTC, the local police, and other parties listed on the emergency contingency plan in case of accidents or spills and clean up the contamination according to the spill response plan. The waste transporter must file within five (5) days a detailed Incident Report to the same EMB Regional Office, describing the accident, spill, and containment or clean-up measures taken.
- Include the shipping vessel in the Hazardous Waste Manifest System in case of inter-island shipment

4.7 STORAGE AT STORAGE DEPOT

Storage facility requirements for waste generators, transporters, and TSD facilities are provided by DAO 2013-22. These include:

- Accessibility in cases of emergency and for purposes of inspection and monitoring;
- Adequate ventilation;
- Have floors that are impermeable to liquids and resistant to attack by chemicals, not slippery, and constructed to retain spillages;
- Security from unauthorized persons;
- Have provision for proper waste segregation in accordance to their chemical properties and waste type;
- Have provision for proper drum handling and storage as described in the following:
  - Drums are stored in upright position on pallets and stacked no more than two (2) drums high.
  - Drums are raised on pallets or similar structures to allow passage of water and circulation of air.
  - Checking for leakages.
  - Storage of filled drums on their side and should not be stacked.
  - Observance of adequate safety precautions when handling drums filled with hazardous materials.
- Availability of full emergency response equipment corresponding to the class of wastes being stored and potential emergencies associated with it; and
- Ensure that all categories of wastes allowed to be stored within a prescribed period are treated or sent to appropriate TSD facilities. Otherwise, the storage facility owner or manager shall clean up the area and dispose the waste to prevent environmental damage.

4.8 TREATMENT AND/OR DISPOSAL

Similar to waste generators and transporters, there are other requirements in opening a TSD facility other than registering online with the EMB:

- ECC, Permit to Operate and Discharge Permit for the TSD facility;
- Environmental Guarantee Fund in the form of commercial insurance, surety bond, trust fund, or a combination thereof, whose amount is

commensurate to the identified risks (from the Risk Assessment Studies] and callable upon demand by the Department during spill or emergency;

- Process flow and detailed description of each treatment, recycling, disposal process technology including overall material balance identifying all by-products, end-products and residues;
- Wastes acceptance criteria and procedure to ensure that the TSD facility shall not accept wastes beyond its capacity, including quantity and quality;
- In case of recycling and recovery facility, recovered material or product shall meet the product standard;
- Storage Management Plan for raw materials, residues, by-products and end- products;
- Long-term plan for the recycled, processed, recovered and end-products;
- Contingency and Emergency Plan based on Hazard Identification and Risk Assessment Studies; and
- Valid contract with a registered Transporter(s).

4.8.1 Minimum Considerations for Siting TSD Facilities

The following guidelines, standards, and criteria shall be applied in siting TSD Facilities:

- Consistent with the overall land use plan of the LGU;
- Accessible from major roadways and thoroughfares; and
- Located in an area where the TSD operation will not detrimentally affect sensitive resources, such as aquifers, groundwater reservoirs, watershed areas, by provision of the following special mitigating measures and additional criteria:
  - Shall not be constructed within 75 meters from a Holocene fault or known recent active fault
  - Shall not be located in areas where they are known to be habitat of listed endangered species
  - Shall not be located in a floodplain and reclaimed areas
  - Shall be located at least 50 meters away from any perennial stream, lake or river
  - Groundwater monitoring wells shall be placed at appropriate locations and depth that are representative of groundwater quality and for predicting groundwater flow

4.8.2 Waste Acceptance Criteria

The EMB has divided TSD facilities into six (6) categories. The table below lists the categories that may accept mercury and mercury compounds:

Aside from category, TSD facilities are restricted to only accepting wastes which comply with requirements set by the EMB. These requirements are:

- Notification to the TSD facility through the Online Hazardous Waste Manifest System and compliance to its requirements;
- Containers are properly labelled as to the type of wastes and the corresponding potential hazards;
- Independent random analysis undertaken by the TSD facility to verify the type of wastes indicated in the manifest; and
- Wastes are not transported by the transporter indicated in the manifest.

TSD facilities must refuse receiving any waste which does not satisfy the above requirements. TSD facilities are not authorized to store such wastes even in the interim until the issue is resolved. Furthermore, TSD facilities must immediately report such incidents to the EMB Central and Regional offices that have jurisdiction

Table 21 **Categories of TSD Facilities**

Category	Description
A	Facilities that conduct onsite treatment and disposal of hazardous wastes generated within the Facility that employs or utilizes technologies from Categories B to E
C	Landfills that only accept hazardous wastes for final disposal C.1 Facilities that accept only inert or treated hazardous wastes for final disposal in a dedicated cell C.2 Facilities that accept hazardous wastes for final disposal such as solidified, encapsulated wastes, etc. under Class K of this procedural manual
D	Facilities that recycle or reprocess hazardous waste, which are not generated or produced at the facility D.1 Facilities include those that recover valuable materials, i.e. used or waste oil, solvents, acids, alkalis, metals, etc.
E	Facilities that accept and treat hazardous not generated or produced at the facility using immobilization, encapsulation, polymerization, or similar processes. Facilities include those that receive hazardous wastes outside the premises and transform physical or chemical characteristics of the hazardous wastes by physico-chemical or thermal treatment to dispose them into facilities in Category C.
F	Facilities that store hazardous wastes, which were not generated from the facility awaiting transport for treatment, disposal, or export such as: F.1 Material Recovery Facilities F.2 Buildings that store containers, vessels, or tanks containing hazardous wastes

over the waste generator, transporter, and TSD facility.

4.9 EXPORT

The Philippine government allows the export of hazardous wastes to other nations who are signatories to the Basel Convention or have existing agreements with the Philippines in terms of transboundary movement of hazardous wastes. With this, organizations may export discarded MAPs out of the Philippines as long as the process is in accordance with the provisions of the Basel Convention and RA 6969.

All exporters of hazardous wastes shall be required to:

- Submit Notification for EMB's transmittal to the Competent Authority of the importing and transit countries
- Designate a PCO
- Comply with all the requirements of the Basel Convention
- Comply with the transport record or manifest system to convey the exporting hazardous waste and recyclable materials containing hazardous substances from the generator to the port of embarkation after securing an Exportation Clearance and Permit
- Comply with the storage and labelling requirements as described DAO 2013-22
- Require that the shipment be accompanied by the movement document from the point at which a transboundary movement commences to the point of disposal
- Provide written consent on the transboundary movement of hazardous waste and/or

recyclable materials containing hazardous substances from each State of transit, if applicable

- Provide written confirmation of the existence of a contract between the exporter and the disposer specifying environmentally sound management of the wastes in question from the State of import

- Provide written confirmation of the existence of financial guarantee to cover cost for re-import or other measures that may be needed

4.10 MONITORING

DAO 2013-22 established a manifest system which enables monitoring of wastes.

4.10.1 Waste Generator Manifest Form

Once a waste generator is ready to have its hazardous wastes transported to an off-facility treatment site, it has to request approval from the EMB through the Online Hazardous Waste Manifest System. The request is sent by filling-out and submitting the Waste Generator Manifest Form. Included in the information collected by the form are the names of the registered hazardous waste transporter and TSD facility contracted by the waste generator. Note that only registered companies may be contracted to transport and treat hazardous waste. Once the application has been approved, the EMB shall send a Notice of Acceptance to the waste generator as well as to the indicated waste transporter in the manifest form.

4.10.2 Transporter Manifest Form

After receiving the notice of acceptance from the EMB, the waste transporter must go to the online Hazardous Waste Manifest System and fill-out and submit the Transporter Manifest Form. If the EMB approves the submission, it will issue the Hazardous Waste Manifest Acknowledgement Letter. This document will allow the transporter to transport the waste to the TSD facility indicated in the manifest form.

4.10.3 Treater Manifest Form

Upon receiving the Notice of Acceptance from the EMB, the TSD facility must go to their account in the online Hazardous Waste Manifest System and fill-out and submit the manifest form. The submitted form must specify the exact date the wastes are received from the waste transporter indicated in the manifest form.

Within 45 days from receipt of the wastes, the TSD facility shall fill in the required portion in the Manifest Form, and issue the Certificate of Treatment (COT). The EMB Regional Office shall then evaluate the Treater Manifest Form and, upon approval, issue Acceptance Letter and close-out the Manifest Form.

NEXT STEPS

Table 22 **Gap analysis matrix**

Focused area/s for analysis	International guidelines and best practices	Current Philippine policy and guidelines
Life Cycle Stages		
Waste prevention and minimization	The Basel Convention highlights the primary of waste minimization and prevention in the ESM hierarchy. When prevention and minimization have been exhausted, BAT, BEP and life-cycle approach is encouraged Article 4 of the Minamata Convention prohibits the manufacture, import and export of MCMMDs starting 2020. Examples of phase out regulations are in place in countries such as the US, the European Union and Canada. Alternatives to MCMMDs are already available and in use in countries. At the global level, Article 4 para 4 of the Convention directs the Secretariat to collect and maintain information on MAPs and their alternatives, making these information publicly available. WHO Technical Specifications on mercury-free thermometers and sphygmomanometers which can be used in procurement policies are already in place. Considerations for the successful replacement of MCMMDs in the healthcare settings are elaborated in section 3.2 of the report.	The existing Philippine policy framework puts a great emphasis on waste prevention and minimization as the priority strategy for the ESM of chemicals and hazardous waste. the country has long-standing provisions prohibiting the manufacture, import, use and export of MCMMDs, such as the DOH AO 2008-21, which established the phaseout of MCMMDs in healthcare facilities in the Philippines. The updated CCO on mercury specified the phaseout schedule for such MAPs, indicating that MCMMDs will be considered as mercury wastes intended to be disposed of in an environmentally sound manner by 2022. However, results of the parallel inventory show purchase of MCMMDs of some healthcare facilities in the last five years. In terms of mercury-free alternatives, the DOH AO covers the development and implementation of a purchasing policy, whereas the CDRRHR technical specifications for thermometers, a regulated medical device, reflected the transition to mercury-free alternatives. While these phase out policies are being implemented, support to regulatory agencies responsible for monitoring implementation (e.g., FDA, BOC) should be provided.

5.1 IDENTIFIED GAPS

Table 22 shows the identified gaps between the international guidelines and best practices and the current guidelines for the ESM of MCMMDs in the Philippines. Gaps include difference between policy provisions as well as the implementation challenges documented in the situation assessment report developed in parallel with this document.

5.2 ACTIONS

Policy and programmatic actions were identified in Table 22, and were further fleshed out in the Table 23:

Identified gaps	Policies/ programs/ technical guidelines needed
Generally, the current policy framework contains comprehensive provisions on mercury waste prevention and minimization. Pending policy provisions to be considered include: 1. Finalization of the draft FDA circular phasing out MCMMDs, to control retail sales of mercury thermometers and sphygmomanometers especially through online channels. 2. Inclusion of sphygmomanometers in the list of regulated medical devices of the FDA CDRRHR, integrating WHO technical specifications. 3. Assistance to regulatory agencies' registration as waste generator and capacity-building (e.g. FDA, BOC) Other than the above, enforcement/ implementation remains to be the main issue. Discrepancies on the records of the DOH HFSRB and the parallel inventory in terms of the purchasing activity of MCMMDs needs to be explored.	Finalization of the draft FDA circular phasing out MCMMDs, to control retail sales of mercury thermometers and sphygmomanometers especially through online channels Inclusion of sphygmomanometers in the list of regulated medical devices of the FDA CDRRHR, integrating WHO technical specifications Compliance to the phase-out provisions of DOH AO 2008-21 and the CCO could be facilitated by any of the following actions: 1. DENR or DOH notifying the targeted healthcare facilities to comply with the phaseout and/or imposing sanctions/ penalties for non-compliance; and/or 2. DENR, DOH or Philhealth to encourage compliance through non-financial incentives This can be coupled with: 1. Improving the technical knowledge and capacity of healthcare facility representatives with regard to the provisions of the law; and 2. Providing administrative and logistic support to healthcare facilities. Assistance to regulatory agencies' registration as waste generator and capacity-building

Focused area/s for analysis	International guidelines and best practices	Current Philippine policy and guidelines
Inventories	The Basel Convention notes the need for Parties to define wastes to be considered as hazardous under national legislations (Article 3). The Minamata Convention identify three categories of mercury wastes, namely wastes consisting of, containing or contaminated with mercury or mercury compounds (Article 11). The Basel Technical Guidelines note that there is no thresholds for mercury wastes falling under Article 11. Methodologies developed by UN agencies for conducting inventory are provided in section 3.3 of the document. Inventory is crucial to identify and prioritize issues and enable effective action to prevent, minimize and manage mercury wastes.	Due to their phaseout in the healthcare setting, MCMMDs are considered as hazardous wastes in the Philippines. Based on DAO 2013-22, these devices are classified under category D407 or mercury and mercury compounds, and are defined as containing mercury concentration of more than 0.1 mg/L. Inventory activities were done in 2008 and 2019, following the UNEP Toolkit. Potential sources of inventory data also include the mercury audit required by DOH AO 2008-21, and the manifest system required by DAO 2013-22. However, records-keeping of mercury audit information remain to be weak, whereas the manifest system of DAO 2013-22 does not distinguish among D407 wastes.
Packaging and labelling	Packaging and labeling guidelines are discussed in detail in sections 3.4 and 3.5. Note that the guidelines distinguish between the packaging of waste MAPs and the packaging of waste consisting of mercury (for mercury extracted from MAPs). Global standards to follow include the GHS and the UN Recommendations on the Transport of Dangerous Goods.	Packaging and labeling guidelines are discussed in detail in section 4.3 and 4.4, which includes compliance to GHS and export standards. However, review of the implementation of DOH AO 2008-21 show some healthcare facilities that are unable to follow packaging and labeling guidelines.
Handling, separation and collection	The detailed guidelines for the handling, separation and collection of mercury wastes are provided in sections 3.7, which are mostly collated from the Basel Convention Technical Guidelines. Most notable among the guidelines are the options for collection schemes for waste MAPs, which include: ▪ establishing waste collections stations ▪ collection at public places ▪ coordinated collection ▪ prepaid shipping service	No collection system are in place for MCMMDs, as healthcare facilities are required, as waste generators, to facilitate disposal by contacting waste transporters and TSD facilities.
Storage (temporary on-site and off-site/ at storage depot)	Guidelines on on-site and off-site storage are discussed in section 3.6 and 3.8. Specific guidelines are given depending on the function of the storage (e.g., on-site storage at healthcare facilities or off-site storage in a centralized hazardous waste management facility).	Guidelines on on-site and off-site storage are discussed in section 4.5 and 4.7. However, review of the implementation of DOH AO 2008-21 and the results of the parallel inventory show some healthcare facilities that are unable to follow interim storage guidelines.

Identified gaps	Policies/ programs/ technical guidelines needed
To facilitate a more comprehensive inventory of mercury wastes, the classification of mercury wastes need to be articulated and aligned with the definition and categories of the Minamata Convention. This includes removing the threshold values for mercury wastes falling under Article 11. The adoption of this classification will also allow the mercury audit and the DAO 2013-22 manifest system to distinguish among several mercury waste. Inventory activities using the UNEP Toolkit can be improved by using country-specific input factors.	The DAO 2013-22 can be amended to adopt the definition and classification of the Minamata and Basel Conventions on mercury waste. This will allow the manifest system to distinguish among mercury wastes, particularly MCMMDs, allowing the establishment of a traceability chain and an inventory.
No policy gap was found. However, compliance with guidelines need to be strengthened.	Compliance could be facilitated by any of the following actions: ▪ DENR or DOH notifying the targeted healthcare facilities to comply with guidelines and/or imposing sanctions/ penalties for non-compliance; and/or ▪ DENR, DOH or Philhealth to encourage compliance through non-financial incentives
No collection system are in place for MCMMDs, as healthcare facilities are required, as waste generators, to facilitate disposal by contacting waste transporters and TSD facilities. The respondents of the study conducted by Zordilla (2018) considers the implementation of final disposal of mercury wastes stored in hospitals (i.e., collection of MCMMDs) as key in increasing effectiveness of the phaseout program. Interview with the DOH representative noted that collection can be coursed through the CHDs (regional offices).	A programmatic approach can be done to facilitate a one-time collection scheme for the remaining MCMMDs through the CHDs of the DOH. Administrative and logistic support is still needed for them to comply with the requirements as waste generators and to facilitate the linkage with accredited transporters and TSD facilities. (Note: the development of the collection scheme can consider options for collecting MCMMDs in households and/or other waste MAPs in household/ healthcare settings. However, coordination with other stakeholders (e.g. LGUs, etc.) must be done.
While DAO 2013-22 does not delineate between the size and function of the storage, DOH AO 21-2008 provides guidelines for healthcare facilities may be storing only small amounts of wastes. Compliance with guidelines need to be strengthened. Some facilities still have MCMMDs stored beyond the storage limit (with extension up to two years) imposed by DAO 2013-22. Exemptions cannot be considered since other facilities were able to dispose of their wastes.	Compliance could be facilitated by any of the following actions: ▪ DENR or DOH notifying the targeted healthcare facilities to comply with guidelines and/or imposing sanctions/ penalties for non-compliance; and/or ▪ DENR, DOH or Philhealth to encourage compliance through non-financial incentives

Focused area/s for analysis	International guidelines and best practices	Current Philippine policy and guidelines
Transportation of mercury wastes	More specific guidelines are discussed in section 3.7, which include the requirements for licensing transporters and the requirements for personnel to be involved and vehicles to be used. A notable guideline include setting an upper limit to which a licensed transporter is needed.	More specific guidelines are discussed in section 4.6 which include the requirements for licensing transporters and the requirements for personnel to be involved and vehicles to be used set by DAO 2013-22.
Environmentally sound disposal	The Basel Convention lists both recovery and disposal operations that can be adopted for the environmentally sound disposal of mercury wastes. Several guidance documents note of the criteria for assessing mercury waste disposal and recovery operations (Table 13), while the remainder of section 3.9 delve into the specifics of the technologies for recovery and disposal operations. Note that BAT/ BEP is the main approach for ESM, which will depend on the contexts/ realities of the country.	Guidelines on environmentally sound disposal are provided in section 4.8, which focuses on requirements of TSD facilities that may accept mercury and mercury compounds. Evaluation of TSD technologies are included as part of the ECC application of operators. However, it must be noted that there is no TSD facility in the Philippines that can process MCMMDs. Most of these wastes are exported (to Japan) for final recovery, treatment and disposal using pyro-metallurgical processes. Results of the parallel inventory show that some MCMMDs have been disposed of in the early days of the DOH AO 2008-21, but some still remain healthcare facilities.
Export/ transboundary movement	Article 11 para 3 (c) of the Minamata Convention notes that transboundary movement should occur for the purpose of environmentally sound disposal. The Technical Guidelines further notes that the transboundary movements of hazardous waste must be permitted only under the following conditions: ▪ if the country of export does not have the technical capacity to manage the ESM of the waste; ▪ if the waste in question are required as raw material for recycling or recovery in the country of import; or ▪ if the transboundary movement in question is in accordance with other criteria set by the Parties The list of required documents, as well as the process is provided in section 3.10. It should be noted that export might be a cheaper solution than the alternatives (e.g., SEL, permanent underground storage), however, there are only five service providers that can treat MCMMDs. Only one of them (Nomura Kohsan Co., Ltd) are within the Asian region.	The Philippine government allows the export of hazardous wastes to other nations who are signatories to the Basel Convention or have existing agreements with the Philippines in terms of transboundary movement of hazardous wastes. The requirements and procedures for the export of waste is provided in section 4.9.

Identified gaps	Policies/ programs/ technical guidelines needed
The existing policy does not indicate an upper limit to which a licensed transporter is needed.	The DAO 2013-22 can be amended to adopt an upper limit to which a licensed transporter is needed. US EPA regulations 40 CFR 261.5 and regulations 49 CFR 173.164 note that small quantity generators (e.g. hospital, clinic, other health facility) can use their own vehicles when transporting less than 100 kilograms of mercury-containing waste, or 0.45 kilograms of elemental mercury, respectively. Waste quantities above this limit would require a licensed transporter and a registered vehicle.
No policy gap was found. However, compliance with guidelines need to be strengthened, especially for waste generators.	A programmatic approach can be done to facilitate a one-time collection scheme for the remaining MCMMDs through the CHDs of the DOH. Awareness-raising among healthcare facilities can also be done to inform them of disposal options.
The current policy framework contains comprehensive provisions on transboundary movement. Additional action can include linking the manifest system to the movement document.	A programmatic approach can be done to facilitate a one-time collection scheme for the remaining MCMMDs through the CHDs of the DOH. Awareness-raising among healthcare facilities can also be done to inform them of disposal options, including export for disposal. Cost-benefit analysis of disposal options can also be done as part of the program.

Focused area/s for analysis	International guidelines and best practices	Current Philippine policy and guidelines
Monitoring mechanism	Traceability of mercury wastes is also emphasized as an important aspect of ESM, which includes record keeping of pertinent information regarding the waste. More information is found in section 3.11	Traceability is established through the manifest system required by DAO 2013-22 (see section 4.10). However, the manifest system does not distinguish among D407 wastes. Other monitoring mechanisms include SMRs and inspection reports.
Financial resources and mechanisms	Article 13 of the Minamata Convention calls on Parties to provide, within its capabilities resources for national activities that are intended to implement its obligations. In addition, the Convention encourages the establishment of multilateral, regional and bilateral sources of financial and technical assistance to enhance and increase activities of developing nations toward the implementation of the Convention	The existing policy framework puts the burden of cost for the ESM of MCMMDs on the waste generators. The NAP articulates the budget requirements for relevant Convention activities, and have identified some activities that can be funded as part of the regular operations of the agencies. Some activities were noted to require external funding sources.
Identification of stakeholders	The ESM Framework notes the crucial role of the Government in the development, implementation, monitoring and evaluation of an ESM policy. In addition, it recognizes the roles of: ▪ Waste generators ▪ Waste carriers ▪ Waste dealers and brokers ▪ Waste management facilities which should account for the whole life cycle management of mercury.	All legislations clearly identify the stakeholders involved in the ESM of chemicals and wastes. This includes the identification of government agencies and stakeholders composing interagency committees/ groups. DAO 2013-22 also articulates the roles and responsibilities of waste generators, transporters, and TSD facilities.
Public and worker safety	Article 16 of the Minamata Convention encourages Parties to promote the development and implementation of strategies and programs to protect and identify vulnerable populations, promote science-based educational programs, promote, healthcare services for mercury treatment and exposure prevention, among others. Section 3.14 identifies the specific activities needed to protect public and workers' health and safety. For worker health and safety, establishment of exposure limits are crucial.	Guidelines on the ESM of mercury and mercury wastes integrate the concept of the protection of public health against the adverse effects of mercury. Appropriate training is also required to capacitate workers involved in the waste management process. In addition, the Occupational safety and Health Center (OSHC) has recently recommended an amendment to the threshold limit value (TLV) for mercury in the workplace from 0.05 to 0.025 mg/m3.

Identified gaps	Policies/ programs/ technical guidelines needed
To facilitate a more comprehensive traceability chain, the classification of mercury wastes need to be articulated and aligned with the definition and categories of the Minamata Convention. This includes removing the threshold values for mercury wastes falling under Article 11. The adoption of this classification will also allow the mercury audit and the DAO 2013-22 manifest system to distinguish among several mercury waste.	The DAO 2013-22 can be amended to adopt the definition and classification of the Minamata and Basel Conventions on mercury waste. This will allow the manifest system to distinguish among mercury wastes, particularly MCMMDs, allowing the establishment of a traceability chain and an inventory. Streamlining of monitoring mechanisms (i.e., integrating SMRs, inspection reports and manifest system in one platform) can also be explored, and can be linked with the licensing process for health facilities.
Since the existing policy framework puts the burden of cost for the ESM of MCMMDs on the waste generators, compliance can be difficult for healthcare facilities in low-resource setting.	A programmatic approach can be done to facilitate a one-time collection scheme for the remaining MCMMDs through the CHDs of the DOH. This can be supported by external funding sources if domestic funding is not available.
No policy gaps are identified. The existing framework clearly articulates the roles and responsibilities of government agencies, as well as the waste generators, transporters, and TSD facilities.	No further policy action. Continued engagement with stakeholders are already in place in the NAP. However, indicators measuring this should be included in the M&E of NAP activities.
No policy gaps are identified.	No further policy action. Programs to strengthen public and worker safety through capacity building and information dissemination are already in place in the NAP. However, indicators measuring this should be included in the M&E of NAP activities.

Focused area/s for analysis	International guidelines and best practices	Current Philippine policy and guidelines
	Other Elements for Consideration	
Development of implementation plans	Article 20 of the Minamata Convention provides for the development of a NIP, which is an optional tool that can assist countries in fulfilling their obligations under the convention. Guidance documents developed by WHO and other stakeholders enumerate strategies for implementation including: ▪ developing a stakeholder engagement plan ▪ conducting a situation assessment and inventory ▪ development of specific intervention packages ▪ establishment of monitoring and reporting mechanisms	The NAP details the 5-year implementation plan for the ESM of mercury-containing products in accordance with the provisions of the Minamata and Basel Conventions. It is a result of consultations and workshops with stakeholders, which included a situation assessment and inventory (through the UNEP Level 2 Toolkit). The NAP also includes a review of the implementation of the NAP and its subsequent updating.
Capacity-building and human resources	Capacity-building and human resources is an important component of ESM. Throughout chapter 3, the content of training programs for each stakeholder (from generators to TSD facilities) are provided, and serve as requirements for the issuance of licenses and permits.	Throughout section 4.3, the content of training programs for each stakeholder (from generators to TSD facilities) are provided, and serve as requirements for the issuance of licenses and permits.
Public information, awareness and education	The generation and sharing of information is an important pillar in the effective implementation under the Minamata Convention. Several articles can be used as a guide to identify the types of information that need to be disseminated, such as Article 17 (Information Exchange), Article 18 (Public Information, Awareness and Education) and Article 19 (Research, Development and Monitoring).	All national legislations, including the AOs integrate provisions for public information, awareness and education for the ESM of chemicals and waste (Table 19). In addition, the NAP for MAPs list the specific public campaigns that can be done to reach a broader audience, including integrating ESM principles in the K to 12 health curriculum, launching essay/ poster-making contests, use of radio programs, among others.
Evaluation and effectiveness of programs and policies	▪ The Basel Convention Technical guidelines enumerates the examples of indicators that can be used at the governmentand facility-level, as indicated by the Basel Convention ESM Framework.	The NAP articulates the development and implementation of an M&E strategy for NAP activities.

Identified gaps	Policies/ programs/ technical guidelines needed
No policy gaps are identified.	No further policy action. A review of the implementation of the NAP and its subsequent updating is already in place in the NAP. Indicators measuring this should be included in the M&E of NAP activities.
No policy gaps are identified.	No further policy action. Programs to strengthen capacity-building and human resources are already in place in the NAP. However, indicators measuring this should be included in the M&E of NAP activities.
No policy gaps are identified.	No further policy action. Programs to strengthen public information, awareness and education are already in place in the NAP. However, indicators measuring this should be included in the M&E of NAP activities.
No policy gaps are identified.	▪ No further policy action. The development of an M&E strategy is already in place in the NAP. Indicators that can be used at the government- and facility-level can be found in section 3.4.8.9.

Table 23 **Proposed policy and programmatic actions**

Proposed Actions/ Guidelines	Category
Short description of the policies/ programs and/or outline of technical guidelines	Identify whether C= current measure; OT= obligatory-time-limited; OF=obligatory-flexible timing; V=voluntary
Finalization of the draft FDA circular phasing out MCMMDs, to control retail sales of mercury thermometers and sphygmomanometers especially through online channels	▪ Policy - OT
Support to regulatory agencies responsible for monitoring implementation (e.g., FDA) should be provided, including registration as waste generator.	Programmatic – OT
Inclusion of sphygmomanometers in the list of regulated medical devices of the FDA CDRRHR, integrating WHO technical specifications	▪ Policy - OF
Actions to encourage/ trigger compliance of healthcare facilities to the provisions of DOH AO 2008-21, CCO, and DAO 2013-22 on the phaseout of MCMMDs and their proper packaging, labeling, storage, transport, and disposal. These include: ▪ DENR or DOH notifying the targeted healthcare facilities to comply with the phaseout and/or imposing sanctions/ penalties for non-compliance; and/or ▪ DENR, DOH or Philhealth to encourage compliance through non-financial incentives	OT
Amendments to DAO 2013-22: ▪ - adoption of the definition and classification of the Minamata and Basel Conventions on mercury waste ▪ adoption of upper limit to which a licensed transporter is needed ▪ Streamlining of the monitoring and reporting process (i.e., integrating SMRs, inspection reports and manifest system in one platform) and can be linked with the licensing process for health facilities.	▪ Policy - OT
Development of a program to establish one-time collection and final disposal of remaining MCMMDs in healthcare facilities, through support of DOH CHDs and funding from external sources. Component activities include: ▪ providing administrative and logistic support to comply with requirements (e.g., DAO 2013-22) ▪ analysis of the costs of the collection scheme and disposal options	▪ Programmatic - OT
Implementation of activities identified in the NAP, including monitoring and evaluation	▪ Programmatic - mix of OF and V

	Target Stakeholders	Target Date of Implementation
	Identify lead office/ agency/ focal points and relevant offices/ agencies/ focal points stakeholders involved	Identify target date/s of implementation and relevant milestones
	Lead agency: FDA Stakeholders: Members of IATWG, manufacturers, importers, distributors, sellers of target medical devices, online selling platforms, among others	NAP date: Q1 2020 New target date: within 2021
	Lead agencies: DENR and FDA Stakeholders: Members of IATWG	(To be determined in the stakeholder workshop)
	Lead agency: FDA Stakeholders: Members of IATWG, manufacturers, importers, distributors, sellers of target medical devices, among others	(To be determined in the stakeholder workshop)
	Lead agencies: DENR and DOH Stakeholders: Members of IATWG, waste generators (i.e., healthcare facilities), transporters and TSD facilities	(To be determined in the stakeholder workshop)
	Lead agency: DENR Stakeholders: Members of IATWG, waste generators (i.e., healthcare facilities), transporters and TSD facilities	Currently in progress; final timelines to be determined in the stakeholder workshop
	Lead agencies: DENR and DOH Stakeholders: Members of IATWG, waste generators (i.e., healthcare facilities), transporters, TSD facilities, and development partners (regional/ global). Additional stakeholders may be included should other waste sources (e.g. households) or waste types (i.e., other MAPs) be included in the scheme	(To be determined in the stakeholder workshop)
	Lead agency: DENR Stakeholders: Members of IATWG, waste generators (i.e., healthcare facilities), transporters, TSD facilities, development partners, general public	Specific timelines already identified in the NAP. However, these can be updated during the stakeholder workshop.

ANNEX

ANNEX A. WHO Technical Specifications for Mercury-Free Thermometers (WHO, 2020a)[57]

INFRARED

i	Version no.	1
ii	Date of initial version	6/13/2012
iii	Date of last modification	7/15/2020
iv	Date of publication	
v	Completed/submitted by	WHO working group
		Name, category or coding
1	WHO category/code	(under development)
2	Generic name	Thermometer, infrared, skin
3	Specific type or variation (optional)	Skin
4	GMDN name ©	Infrared thermometer, skin
5	GMDN code ©	17888
6	GMDN category ©	04 Electro mechanical medical devices
7	UMDNS name ©	Thermometers, Electronic, Infrared, Skin
8	UMDNS code ©	17888
9	UNSPS code (optional) ©	
10	Alternative name/s (optional)	Clinical electronic thermometer
11	Alternative code/s (optional)	MS 34341
12	Keywords (optional)	temperature, fever
13	GMDN/UMDNS definition (optional) ©	A handheld, battery-powered, electronic instrument designed to estimate the temperature of a site on the skin (e.g. axilla, forehead) by measurement of body infrared emissions at this particular point. It provides a method to determine temperature patterns or variations on the surface of the skin (e.g. due to differences in perfusion). This device may be used in the home. This is a reusable device.
14	CND code (https:// ec.europa.eu/health/ md_topics-interest/ overview_en)	V03010102
15	CND nomenclature	ELECTRONIC THERMOMETERS AND END CAPS
		Purpose of use
16	Clinical or other purpose	Estimate the temperature of a site on the skin.
17	Level of use (if relevant)	Health post, health centre, district hospital, provincial hospital, specialized hospital, outreach (mobile clinics)
18	Clinical department/ward (if relevant)	Emergency room (ER), neonatal intensive care unit (NICU), surgery, outpatient, intensive care unit (ICU), hospital triage and other departments

57 Ibid. 30

19	Overview of functional requirements	Displays patient temperature by measurement of infrared radiation from the skin. Device must be reusable, with sterilizable surface. Display should be easily readable in all levels of ambient light.
		Technical characteristics
20	Detailed requirements	Specified accuracy to be not higher than 0.2–0.3 °C. Measurement range at least from 30–43 °C. High/low patient temperature display feature preferred. Auto power off required after minimum of 1 minute. Out of range indication required. Response (measurement) time not higher than 3 sec. Ready-to-use after switch-on in a time not higher than 10 sec. Infrared (IR) spectral response 6000–14 000 nm. Optimal measuring distance approximately 8–12 cm/4–6 inch. Equipment factory calibrated and pre-set emissivity data for all skin types. Automatic self-test on switch-on. Video and/or audio alert/signal at least for the following cases: switch-on, ready-to-use and measurement completed.
21	Displayed parameters	Display graded in 0.1/0.3 °C steps. High/low patient temperature. Low battery. Malfunction. °F or °C measurement units.
22	User adjustable settings	None.
		Physical and chemical characteristics
23	Components (if relevant)	Supplied in protective case for clean storage and safe transport. Unit case should be hard and splashproof. Must be lightweight and comfortable to hold. There must be no sharp edges on the unit.
24	Mobility, portability (if relevant)	Easy and safe transport to be possible by hand.
25	Raw materials (if relevant)	N/A
		Utility requirements
26	Electrical, water and/or gas supply (if relevant)	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to open. Battery to allow at least 4000 measurements between charges. Battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
		Accessories, consumables, spare parts, other components
27	Accessories (if relevant)	Full range of any adaptors required to allow for measurement of all ages of patient.
28	Sterilization process for accessories (if relevant)	Not required.
29	Consumables/reagents (if relevant)	Not required.
30	Spare parts (if relevant)	Replacement battery pack, supplied empty of charge.
31	Other components (if relevant)	
		Packaging
32	Sterility status on delivery (if relevant)	N/A
33	Shelf life (if relevant)	N/A
34	Transportation and storage (if relevant)	Unit shall be supplied protectively packed for safe transportation and delivery.
35	Labelling (if relevant)	N/A

		Environmental requirements
36	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
		Training, installation and utilisation
37	Pre-installation requirements (if relevant)	Not required.
38	Requirements for commissioning (if relevant)	Safety and operation checks before handover.
39	Training of user/s (if relevant)	Training of users in operation and technicians in basic maintenance.
40	User care (if relevant)	The whole unit is to be cleanable with alcohol or chlorine wipes or with any standard hospital disinfection procedure/material.
		Warranty and maintenance
41	Warranty	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
42	Maintenance tasks	List of procedures required for local routine maintenance should be provided.
43	Type of service contract	Costs and types of post-warranty service contract available should be described (when needed).
44	Spare parts availability post-warranty	Guaranteed time period of availability of spare parts post-warranty should be pointed out.
45	Software/hardware upgrade availability	Not required.
		Documentation
46	Documentation requirements	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
		Decommissioning
47	Estimated life span	Not less than 5 years.
		Safety and standards
48	Standards, for the manufacturer and the equipment	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). General quality management (e.g. ISO 9001:2015 Quality management systems – Requirements). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
49	Regulatory approval/ certification	Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).

50	International standards	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests ISO 80601-2-56:2009 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement IEC 80601-2-59 Ed. 1.0:2008 (b) Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile EN ISO 15223-1 (EN 980) Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements ASTM E1104-98(2016) Standard Specification for Clinical Thermometer Probe Covers and Sheaths. ASTM E1112-00(2018) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature.
49	Regional and local standards	ANSI/AAMI SP10:2002 and ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-1, Non-invasive sphygmomanometers – Part 1: General requirements DS/EN 1060-2, Non-invasive sphygmomanometers – Part 2: Mechanical sphygmomanometers AS EN 1060.3.2004, Non-invasive sphygmomanometers – Supplementary requirements for electromechanical BP measuring systems GOST R 51959.1, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 1. General requirements GOST R 51959.2, Non-invasive sphygmomanometers. Supplementary requirements for mechanical sphygmomanometers GOST R 51959.3, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems OIML R16-2:2002, Non-invasive automated sphygmomanometers JIS T 1115:2005, Non-invasive automated sphygmomanometers
50	Regulatory framework	Compliance with (where applicable, but not limited to, and latest available version): US regulatory requirements: Code of Federal Regulations, Title 21, Part 820 Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive BP measurement system Japan regulatory requirements: MHLW Ordinance No.16916156000 Aneroid sphygmomanometer European Commission regulatory requirements: Council Directive 93/42/EEC of 14 June 1993 Regulation (EU) 2017/745 of the European Parliament and the Council

DIGITAL

i	Version no.	1
ii	Date of initial version	2013-06-25
iii	Date of last modification	2020-07-21
iv	Date of publication	
v	Completed/submitted by	WHO working group
		Name, category or coding
1	WHO Category / Code	(under development)
2	Generic name	Thermometer, digital
3	Specific type or variation (optional)	Clinical thermometer, non-mercury
4	GMDN name ©	Intermittent electronic patient thermometer
5	GMDN code©	14035
6	GMDN category©	04 Electro mechanical medical devices, 09 Reusable devices, 11 Assistive products for persons with disability
7	UMDNS name©	Thermometers, Electronic; Thermometers, Electronic, Thermistor/ Thermocouple, Patient
8	UMDNS code©	14032; 14035
9	UNSPS code (optional)©	42182200
10	Alternative name/s (optional)	Clinical electronic thermometer; Thermometer, electronic; Thermometer, electronic, clinical; Electronic thermometer; Digital Thermometer
11	Alternative code/s (optional)	MS 34341, 60202046; T 14032, 14032; S 32165, FLL; S 45556, 11138
12	Keywords (optional)	Temperature, fever
13	GMDN/UMDNS definition (optional)©	A handheld, battery-powered, electronic instrument designed to measure a patient's body temperature. It may comprise an electronic unit with an attached probe or be a single unit (shaped like an ordinary handheld capillary thermometer) that detects and converts the changes in temperature into variations of some electrical characteristic, e.g. resistance or voltage. These variations of the electrical characteristics are processed in the electronic circuits and in turn displayed, for a short period, as temperature readings. Thereafter the display will automatically turn off or go into standby mode. This is a reusable device.
14	CND code(https:// ec.europa. eu/health/ md_topics-interest/ overview_en)	V03010102
15	CND nomenclature	ELECTRONIC THERMOMETERS AND END CAPS
		Purpose of use
16	Clinical or other purpose	Designed to measure patient body temperature, used to take periodic body temperature measurements as primary diagnostic indicators.
17	Level of use (if relevant)	Health post, health centre, district hospital, provincial hospital, specialized hospital and outreach (mobile clinics)
18	Clinical department/ ward(if relevant)	Emergency room (ER), neonatal internsive care unit (NICU), surgery, outpatient, intensive care unit (ICU), hospital
19	Overview of functional requirements	Thermistor/thermocouple designed to measure patient body temperature.

		Technical characteristics
20	Detailed requirements	Digital thermometer °C or °F scales available. Safe to use, no glass, no mercury. Measurement range at least from 33–43 °C. Accurate measurement not higher than: ± 0.2 °C between 35–41°C. Liquid crystal display, easy to read. Beep sound and switch off. Response time < 90 sec required. Water proof for ease of cleaning. Supplied with battery. Supplied with clear instructions for use/preventive maintenance. Automatic self-test on switch-on. Ready-to-use after switch-on in a time not higher than 10 sec. Equipment factory calibrated. Auto power off capability required.
21	Displayed parameters	Temperature displayed in steps not higher than 0.3 °C. High/low patient temperature. Low battery indication. Malfunction. °F or °C measurement units.
22	User adjustable settings	N/A
		Physical and chemical characteristics
23	Components(if relevant)	Supplied in protective case for clean storage and safe transport. Unit case should be hard and splashproof. Must be lightweight and comfortable to hold. There must be no sharp edges on the unit. Provided with at least 2 probes (1 spare) capable to be used with any patient and depending on the specific product design.
24	Mobility, portability(if relevant)	Easy and safe transport to be possible by hand.
25	Raw Materials(if relevant)	N/A
		Utility requirements
26	Electrical, water and/or gas supply (if relevant)	Powered by internal, rechargeable, replaceable battery. Battery cover to be secure but simple to clean. Battery to allow at least 4000 measurements between charges. Provided with battery charger to operate from input supply 110–220 V, 60–50 Hz, ± 10% (battery charger built-in or external).
		Accessories, consumables, spare parts, other components
27	Accessories (if relevant)	Full range of any adaptors required to allow for measurement of all ages of patient, if necessary. Supplied in protective case for clean storage and safe transport.
28	Sterilization process for accessories (if relevant)	Not required.
29	Consumables / reagents (if relevant)	Single-use probe cover caps (if applicable, depending on the product design).
30	Spare parts (if relevant)	Replacement battery pack, supplied empty of charge. At least 1 probe capable to be used with any patient, depending on the design of the product (probes cover included when available and applicable).
31	Other components (if relevant)	N/A
		Packaging
32	Sterility status on delivery (if relevant)	Equipment preferably provided with a probe cover by a single-use cap.
33	Shelf life (if relevant)	N/A

34	Transportation and storage (if relevant)	Primary packaging: Unit of use. One (1) thermometer in storage case with manufacturer's instructions for use. Labelling on the primary packaging: Name and/or trademark of the manufacturer. Manufacturer's product reference. Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging. Lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable). Information for particular storage conditions included (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol). Information for handling, if applicable (or equivalent harmonized symbol). Secondary packaging: Protected unit. × clinical thermometers in a box. Labelling on the secondary packaging: Labelling to be the same as primary packaging. Extra information required: Number of units per secondary packaging.
35	Labelling (if relevant)	N/A
		Environmental requirements
36	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0–50 °C and relative humidity of 15–85%, preferably 90%. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85%, preferably 90%.
		Training, installation and utilisation
37	Pre-installation requirements(if relevant)	Not required.
38	Requirements for commissioning (if relevant)	Local clinical staff to affirm completion of installation. Supplier to perform installation, safety and operation checks before handover.
39	Training of user/s (if relevant)	Training of users in operation and technicians in basic maintenance shall be provided.
40	User care(if relevant)	The whole unit is to be cleanable with alcohol or chlorine wipes or with any standard hospital disinfection procedure/material.
		Warranty and maintenance
41	Warranty	Not less than 2 years. Specific inclusions and exclusions to be listed. Contact details of manufacturer, supplier and local service agent to be provided.
42	Maintenance tasks	List of equipment and procedures required for local routine maintenance should be provided.
43	Type of service contract	Costs and types of post-warranty service contract available should be described (when needed).
44	Spare parts availability post-warranty	Guaranteed time period of availability of spare parts post-warranty should be pointed out (when applicable).
45	Software / Hardware upgrade availability	Not required.
		Documentation
46	Documentation requirements	User/technical manual to be supplied in English (provision of versions in other UN languages, if available, will be an asset). Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration, if necessary, and routine maintenance. Battery disposal according local laws.
		Decommissioning
47	Estimated Life Span	Not less than 5 years.

		Safety and standards
48	Standards, for the manufacturer and the equipment	Certified quality management system for medical devices (e.g. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes). Application of risk management to medical devices (e.g. ISO 14971:2019 Medical devices – Application of risk management to medical devices).
49	Regulatory Approval / Certification	"Free sales certificate (FSC). Certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
50	International standards	Compliance to the following international standards, when applicable, or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party). Reference to the last available version is recommended but compliance to previous standards versions could be considered. IEC 60601-1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. ISO 80601-2-56:2009 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. IEC 80601-2-59 Ed. 1.0:2008 (b) Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile. EN ISO 15223-1 (EN 980) Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. ASTM E1104-98(2016) Standard specification for clinical thermometer probe covers and sheaths. ASTM E1112-00(2018) Standard specification for electronic thermometer for intermittent determination of patient temperature.
49	Regional and local standards	ANSI/AAMI SP10:2002 and ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-1, Non-invasive sphygmomanometers – Part 1: General requirements DS/EN 1060-2, Non-invasive sphygmomanometers – Part 2: Mechanical sphygmomanometers AS EN 1060.3.2004, Non-invasive sphygmomanometers – Supplementary requirements for electromechanical BP measuring systems GOST R 51959.1, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 1. General requirements GOST R 51959.2, Non-invasive sphygmomanometers. Supplementary requirements for mechanical sphygmomanometers GOST R 51959.3, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems OIML R16-2:2002, Non-invasive automated sphygmomanometers JIS T 1115:2005, Non-invasive automated sphygmomanometers

50	Regulatory framework	Compliance with (where applicable, but not limited to, and latest available version): US regulatory requirements: Code of Federal Regulations, Title 21, Part 820 Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive BP measurement system Japan regulatory requirements: MHLW Ordinance No.16916156000 Aneroid sphygmomanometer European Commission regulatory requirements: Council Directive 93/42/EEC of 14 June 1993 Regulation (EU) 2017/745 of the European Parliament and the Council

ANNEX B. WHO Technical Specifications for Mercury-Free Sphygmomanometers[58]

MANUAL

TECHNICAL SPECIFICATIONS FOR MANUAL BLOOD PRESSURE MEASURING DEVICES (Including information on the following where relevant or appropriate)		
i	Version No.	2
ii	Date of initial version	
iii	Date of last modification	December 2019
iv	Date of publication	April 2020
v	Completed / submitted by	WHO working group
	Name, category or coding	
1	WHO category or code	
2	Generic name	Sphygmomanometer
3	Specific type or variation (optional)	Aneroid
4	GMDN name ©	Sphygmomanometer, aneroid, manual
5	GMDN code ©	16156
6	GMDN category ©	04 Electromechanical medical devices
7	UMDNS name ©	Sphygmomanometers, aneroid
8	UMDNS code ©	16156
9	UNSPS code (optional) ©	
10	Alternative names/s (optional)	BP meters (sphygmomanometers); BP manometer; aneroid sphygmomanometer
11	Alternative code/s (optional)	MS 30892; MS 43524; S 43839
12	Keywords (optional)	BP, non-invasive, BP set, non-invasive BP, auscultation
13	GMDN/UMDNS definition (optional) ©	A device designed to measure BP consisting of an inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid manometer and tubing. The aneroid manometer consists of a metal bellows, which expands as the pressure in the cuff increases, and a mechanical amplifier that transmits the expansion through a lever to an indicator needle, which rotates around a circular, calibrated scale. The manometer may be mounted on a wall, placed on a table, or handheld (portable); BP measurement is taken in conjunction with a stethoscope.
	Purpose of use	
14	Clinical or other purpose	Diagnosis of hypertension, monitoring of BP
15	Level of use (if relevant)	Screening site, health centre, district hospital, provincial hospital, specialized hospital
16	Clinical department or ward (if relevant)	All areas
17	Overview of functional requirements	Auscultatory, oscillometric or non-invasive BP methods. Inflatable rubber cuff surrounded by durable, flexible cover that can be easily fastened around upper arm Aneroid pressure gauge displaying cuff pressure Pumping bulb and valve that allow adjustment of cuff pressure
	Technical characteristics	

58 Ibid. 29

18	Detailed requirements	Cuff arm fixing method to allow ease of use, ease of cleaning and low attraction of dirt; washable. Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs may vary by manufacturer but should not deviate by ± 5 cm from the stated sizes. Pressure gauge to allow reading of pressure to 2 mm Hg accuracy Maximum pressure, ≥ 300 mm Hg Gauge body to allow recalibration of readings but be sealed and secure in normal operation
19	Displayed parameters	mm Hg
20	User-adjustable settings	
	Physical and chemical characteristics	
21	Components (if relevant)	Rubber tubes to be detachable from other parts, allowing periodic cutting of decayed ends Gauge body to include clip for mounting on cuff Tube length to be > 30 cm Cuff material to be removable and washable To be supplied in protective case
22	Mobility, portability (if relevant)	Portable
23	Raw materials (if relevant)	Not applicable
	Utility requirements	
24	Electrical, water and/or gas supply (if relevant)	Not applicable
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables and reagents (if relevant)	Single-use cuffs in the following sizes: Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). Reusable cuffs in the following sizes: Neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes off the cuffs may vary by manufacturer but should not deviate by ± 5 cm from the stated sizes.
28	Spare parts (if relevant)	Rubber tube (length > 30 cm), reusable cuffs of various sizes
29	Other components (if relevant)	Protective container
	Packaging	
30	Sterility status on delivery (if relevant)	Single-use cuffs must be delivered sterile.
31	Shelf life (if relevant)	Minimum shelf life for single-use cuffs must be 1 year from the date of reception.
32	Transport and storage (if relevant)	Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C
33	Labelling (if relevant)	Not applicable
Environmental requirements		
34	Context-dependent requirements	Can be stored continuously at ambient temperature of 0–50 °C and 15–90% relative humidity. Can operate continuously in ambient temperature of 10–40 °C and 15–90% relative humidity.
	Installation	
35	Pre-installation requirements (if relevant)	
36	Requirements for commissioning (if relevant)	

37	Training of users (if relevant)	Training of users in operation and basic maintenance shall be provided.
38	User care (if relevant)	
	Warranty and maintenance	
39	Warranty	2 years
40	Maintenance tasks	
41	Type of service contract	
42	Availability of spare parts after warranty	5 years after discontinuation by factory
43	Availability of software and hardware upgrades	
	Documentation	
44	Documentation requirements	User, troubleshooting and service manuals must be available to the user and patients in the language(s) of the country in which the device is used and/or in another language authorized by national regulatory agencies. Certificate of calibration and inspection to be provided when purchased. List of equipment and procedures required for local calibration and routine maintenance to be provided. List of important spares and accessories to be provided, with their part numbers and cost Contact details of manufacturer, supplier and local service agent to be provided.
	Decommissioning	
45	Estimated life span	10 years
	Safety and standards	
46	Risk classification	Class A (GHTF Rule 4); Class II (USA); Class I (Australia, Canada and Japan); Class IIa (European Union)
47	Regulatory approval or certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification, by regulatory agency (e.g. by a founding member of IMDRF-EU, USA, Canada, Australia, Japan). Else, approved by local national regulatory agency.

48	International standards	Standards applicable to the product and to the manufacturing process are listed below. Compliance to the last available version of the international standard or to its local equivalent standard is recommended and proof of compliance must be provided. Non-exhaustive list of standards applicable to general quality systems for medical devices: ▪ EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes" ▪ EN ISO 14971:2012, Medical devices – Application of risk management to medical devices ▪ ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and European Union) ▪ ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice ▪ ISO 14971:2007, Medical devices – Application of risk management to medical devices ▪ ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards Non-exhaustive list of standards applicable to manual BP devices: ▪ ISO 81060-1:2007, Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type ▪ ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – Blood pressure monitor) ▪ BS EN 1060-2:1995 +A1:2009, Non-invasive sphygmomanometers: Supplementary requirements for mechanical sphygmomanometers
49	Regional and local standards	ANSI/AAMI SP10:2002 and ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-1, Non-invasive sphygmomanometers – Part 1: General requirements DS/EN 1060-2, Non-invasive sphygmomanometers – Part 2: Mechanical sphygmomanometers AS EN 1060.3.2004, Non-invasive sphygmomanometers – Supplementary requirements for electromechanical BP measuring systems GOST R 51959.1, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 1. General requirements GOST R 51959.2, Non-invasive sphygmomanometers. Supplementary requirements for mechanical sphygmomanometers GOST R 51959.3, Non-invasive sphygmomanometers (Measuring devices of arterial pressure). Part 3. Supplementary requirements for electro-mechanical blood pressure measuring systems OIML R16-2:2002, Non-invasive automated sphygmomanometers JIS T 1115:2005, Non-invasive automated sphygmomanometers
50	Regulatory framework	Compliance with (where applicable, but not limited to, and latest available version): US regulatory requirements: Code of Federal Regulations, Title 21, Part 820 Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive BP measurement system Japan regulatory requirements: MHLW Ordinance No.16916156000 Aneroid sphygmomanometer European Commission regulatory requirements: Council Directive 93/42/EEC of 14 June 1993 Regulation (EU) 2017/745 of the European Parliament and the Council

AUTOMATED

TECHNICAL SPECIFICATIONS OF AUTOMATED NON-INVASIVE BP MEASURING DEVICES WITH CUFF (Including information on the following where relevant or appropriate)		
i	Version No.	1
ii	Date of initial version	1 December 2019
iii	Date of last modification	1 December 2019
iv	Date of publication	31 December 2019
v	Completed or submitted by	WHO working group
		Name, category or coding
1	WHO category or code	To be determined
2	Generic name	Electronic blood pressure monitor
3	Specific type or variation (optional)	Electronic (automated, semi-automated) sphygmomanometer
4	GMDN name ©	Automatic-inflation electronic sphygmomanometer, non-portable
5	GMDN code ©	16173
6	GMDN category ©	Automatic, electronic, oscillometric
7	UMDNS name ©	Sphygmomanometers, electronic, automatic. Sphygmomanometers, electronic, automatic, oscillometric monitors
8	UMDNS code ©	18326, 25209
9	UNSPSC (optional) ©	
10	Alternative names (optional)	Non-invasive BP monitors; oscillometric sphygmomanometers; oscillotonometers; spot check monitors; spot checking; sphygmomanometer, automatic
11	Alternative codes (optional)	
12	Keywords (optional)	Automatic electronic sphygmomanometers non-invasive. Digital automatic non-invasive BP monitor
13	GMDN/UMDNS definition (optional) ©	An electrically powered device designed to non-invasively measure BP, with a self-contained software program to regulate automatic arm-cuff inflation and measurement cycles. It typically displays current heart rate and mean arterial pressure in addition to systolic and diastolic BP; it may have memory to store values and may sound an alarm if BP exceeds pre-set limits. This device is not designed to be portable and is typically used at the bedside.
		Purpose of use
14	Clinical or other	Physical examination; diagnosis of hypertension; monitor, measure and display arterial blood pressure
15	Level of use (if relevant)	Ambulatory care centre, health centre, district hospital, provincial hospital, specialized hospital, home
16	Clinical department or ward (if relevant)	All areas
17	Overview of functional requirements	The main unit includes controls and displays numerical data for BP. It also includes appropriate attached cuffs (probes, and sensors, depending on their configuration) that allow sequential, periodic and/or simultaneous measurements.

		Technical characteristics
18	Detailed requirements	Measurement ranges: systolic (mm Hg), 60–250, 290 preferred for adults, 30–160 for children and 20–120 for neonates. Diastolic (mm Hg), 30–180 adults, 10–150 paediatric, 10100 neonate. Mean arterial pressure (mm Hg), 30–250 adults, 30–160 children, 30–110 neonates. Pulse (beats per min), 30–150 adult and children, 30–180 neonates. Inflation pressure (mm Hg) 150–260 adults, 85–140 neonates; adjustable or automatically set preferred. Auto deflate pressure (mm Hg), 300 adults, 150 neonates. Measurement interval, min: User selectable: ≥ 5 choices. Cuff sizes: neonatal, paediatric, adult, large adult, thigh. Measurement time (s) ≤ 60, user selectable. Automatic 0 required. Display may include tabular and/or graphic trends (user preference). Equipment alarms required: cuff leak, cuff disconnect, failure to take successful reading, low-battery notice. Equipment alarms preferred: hose leak, inflation or deflation error. Sphygmomanometer should automatically deflate if the cuff pressure reaches 300 mm Hg for an adult and 150 mm Hg for a neonate.
19	Displayed parameters	The unit should display the following numerical values: systolic pressure, diastolic pressure, pulse rate and mean arterial pressure. Other parameters are optional. The unit should alert the operator, either visually or audibly.
20	User adjustable settings	Inflation pressure should be adjustable or automatically set according to a previous or current pressure reading or individual requirements. Time between automatic BP measurement cycles should be selectable from at least five values over a range of 1 to 60 min. Set alarm volume and limits within the specified measurement ranges.
Physical and chemical characteristics		
21	Components (if relevant)	Rubber tubes to be detachable from other parts, allowing periodic cutting of decayed ends. Gauge body to include clip for mounting on cuff. Tube length to be > 30 cm. Different cuff sizes available (small or neonate, medium or paediatric, large or adult and extra-large or large adult). Cuff material to be removable and washable.
22	Mobility, portability (if relevant)	Wall, portable, table-top, mobile stand
23	Raw materials (if relevant)	Not applicable
		Utility requirements
24	Electricity, water and/or gas (if relevant)	AC: 120/240, 50/60 Hz DC: Rechargeable battery (for at least 1 h of operation, single-use or rechargeable)
Accessories, consumables, spare parts, other components		
25	Accessories (if relevant)	Mobile stand
26	Sterilization process for accessories (if relevant)	Not applicable
27	Consumables and reagents (if relevant)	Single-use cuffs in the following sizes: neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes. Batteries
28	Spare parts (if relevant)	Rubber tube (length > 30 cm), reusable cuffs in the following sizes: neonatal (10–15 cm), paediatric (14–22 cm), adult (25–36 cm), large adult (34–43 cm), thigh (40–55 cm). The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes. Tubing, valve
29	Other components (if relevant)	Protective case

		Packaging
30	Sterility status on delivery (if relevant)	Single-use cuffs must be delivered sterile.
31	Shelf life (if relevant)	Minimum shelf life for single-use cuffs must be 1 year from the date of reception.
32	Transport and storage (if relevant)	Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C
33	Labelling (if relevant)	With the proper certification and validation requested, plus those required in each country
		Environmental requirements
34	Depend on context	Handling environment temperature: –20 to 60 °C
Installation		
35	Pre-installation requirements (if relevant)	Not applicable
36	Requirements for commissioning (if relevant)	Battery, uninterruptable power source, appropriate cuffs
37	Training of users (if relevant)	All users (physicians nurses, other medical staff) shall have initial training in operation. Biomedical or clinical engineer or technician, medical staff, manufacturer or servicer shall have initial training in operation and basic maintenance by manufacturer, and subsequently if necessary.
38	User care (if relevant)	Clean surface of device and wash reusable cuffs as stated by manufacturer.
		Warranty and maintenance
39	Warranty	2 years
40	Maintenance tasks	Cables and lead wires should be inspected periodically for breaks and cracks.
41	Type of service contract	Not applicable
42	Availability of spare parts after warranty	5 years after discontinuation by factory
43	Availability of software and hardware upgrades	Software upgrade required and if available from factory
		Documentation
44	Documentation requirements	User, troubleshooting and service manuals must be available to the client, preferably in the national language(s) and/or in another language authorized by the national regulatory agency. Certificate of calibration and validation to be provided. List of equipment and procedures required for local calibration and routine maintenance to be provided List of important spares and accessories, with their part numbers and cost, to be provided. Contact details of manufacturer, supplier and local service agent to be provided.
		Decommissioning
45	Estimated life span	10 years
		Safety and standards
46	Risk classification	Depends on the country. Examples: Class A (Global Harmonization Task Force Rule 4); Class II (USA); Class I (Australia, Canada and Japan); Class IIa (European Union)

47	Regulatory approval or certification	Proof of regulatory compliance (e.g. registration, clearance, approval) must be provided as appropriate per the product's risk classification, by regulatory agency (e.g. by a founding member of IMDRF-EU, USA, Canada, Australia, Japan). Else approved by local national regulatory agency.
48	International standards	Standards applicable to the product and to the manufacturing process are listed below. Compliance to the last available version of the international standard or to its local equivalent standard is recommended and proof of compliance must be provided. Non-exhaustive list of standards applicable to general quality systems for medical devices and specific for BPMD: ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes EN ISO 14971:2012, Medical devices – Application of risk management to medical devices ISO 14155:2011, Clinical investigation of medical devices for human subjects – Good clinical practice ISO 14971:2007, Medical devices – Application of risk management to medical devices IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers ISO 16142-1:2016, Medical devices – Recognized essential principles of safety and performance of medical devices – Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards Non-exhaustive list of standards applicable to electronic BP devices: ▪ AAMI/ESH/ISO 81060 Universal Standard for the Validation of Blood Pressure Measuring Devices Non- invasive phygmomanometers – Part 2: Clinical investigation of automated measurement type ISO 81060-2:2018(E) Non-invasive sphygmomanometer standard Part 2: Clinical investigation of intermittent automated measurement type ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – Blood pressure monitor) IEC 80601-2-30:2009 (Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) DS/EN 1060-3 Non-invasive sphygmomanometers – Part 3: Electro-mechanical blood pressure measuring system
49	Regional and local standards	▪ ANSI/AAMI SP10:2002 & ANSI/AAMI SP10:2002/A1:2003 (Manual, electronic or automated sphygmomanometers) DS/EN 1060-3 Non-invasive sphygmomanometers - Part 3: Electro-mechanical blood pressure measuring system GOST R 50267.30 Medical electrical equipment. Part 2. Particular requirements for safety of automatic cycling indirect blood pressure monitoring equipment JIS T 1115:2005 Non-invasive automated sphygmomanometers

50	Regulatory requirements	Compliance with (where applicable, but not limited to, and last available version): USA: ▪ CFR - Code of Federal Regulations, Title 21, Part 820 ▪ CFR - Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive blood pressure measurement system Japan: MHLW Ordinance No. 16916156000 Aneroid sphygmomanometer European Commission: Council Directive 93/42/EEC of 14 June 1993 on Medical Devices Regulation (EU) 2017/745 of the European Parliament and the Council on Medical Devices

ANNEX C. Spill Kit for Small Mercury Spills in a Healthcare Facility

In case of spills, the GEF-funded Global Healthcare Waste Project led by the United Nations Development Programme recommends that healthcare facilities prepare a mercury spill kit containing the following:

Step-by-step instructions	
Personal protective equipment	▪ Several pairs of rubber or nitrile gloves ▪ Safety goggles or protective eyewear § Respiratory protection: ▪ Fit-tested full- or half-facepiece air-purifying respirator with mercury vapor cartridges, or ▪ Face mask with sulfur or iodide impregnated activated carbon, or face mask made of sandwiched activated charcoal-impregnated cloth (Note that face masks that do not seal tightly around the face could allow contaminated air to enter through the edges), or ▪ Other specialty mask or respirator designed particularly for mercury, or ▪ If no specialty masks are available: a face mask with a 0.3 micron HEPA filter to capture amalgam particles and mercury-laden dust (unfortunately, regular masks will NOT protect against mercury vapor) ▪ Coveralls, apron, and other protective clothing ▪ Disposable shoe covers
Containers	▪ Air-tight, sealable plastic bags (small and large sizes, thickness: 2 to 6 mils, or 50 to 150 microns) ▪ Small, air-tight, rigid plastic container with some water or vapor suppression agent for collecting elemental mercury (see recommendation below) ▪ Air-tight, puncture-resistant, rigid plastic or steel jar or container with a wide opening for collecting mercury-contaminated broken glass ▪ Plastic tray ▪ Regular plastic waste bags (thickness: 2 to 6 mils, or 50 to 150 microns)
Tools for removing mercury	▪ Flashlight (electric torch) to locate shiny mercury beads ▪ Plastic-coated playing cards or thin pieces of plastic to push mercury beads into a plastic scoop or pan; if these are not available, use index cards, pieces of cardboard, or stiff paper ▪ Small plastic scoop or plastic dust pan to catch the mercury beads ▪ Tweezers to remove small broken glass pieces ▪ Eyedropper or syringe (without the needle) to draw up large mercury beads ▪ Duct tape or sticky tape to pick up tiny mercury droplets ▪ Vapor suppression agents: ▪ Sulfur powder (available from pharmacies) to absorb mercury by forming mercuric sulfide ▪ Zinc or copper flakes (available from hardware stores) to absorb mercury by forming amalgams - Commercial absorbent pads or vapor suppressants ▪ Brush to remove powder or flakes ▪ Utility knife blade
Materials for decontamination	▪ Vinegar, hydrogen peroxide, and cotton swabs for final cleaning when using sulfur powder ▪ Decontaminant solution or commercial decontaminant ▪ Piece of soap and paper towels
"Danger: Mercury Waste" labels to put on waste containers	

Meanwhile, the following cleanup procedures are recommended:

1. Quickly determine the extent of the spill: Determine on what surfaces the mercury spilled and how far the mercury beads traveled.

2. Immediately block off foot traffic: Do not allow anyone to walk across the contaminated site or to go near areas where the mercury traveled. If the extent of a small spill is not immediately obvious, block off traffic for a radius of about 2 meters around the center of the spill.

3. Contain the spill: If necessary, prevent the mercury beads from traveling further by blocking their path with rags or impervious material. Take steps to keep mercury from falling into drains or cracks. Check

to see if anyone's skin, shoes or clothing was splashed with mercury. If shoes or parts of clothing were contaminated, they should be removed and left around the spill area before allowing the person to leave. Skin that was in contact with mercury should be washed with an alkaline soap.

4. Evacuate the area: Ask everyone to leave the room or the general area, giving priority to pregnant women and children. Seek assistance to provide first-aid to anyone requiring immediate medical attention.

5. Minimize the spread of vapors to interior areas: Close all interior doors that lead to other indoor areas. Turn off central ventilation, heating or air conditioning systems that circulate air from the spill site to other inside areas of the building.

6. Reduce vapor concentrations in the spill area if possible: After making sure that windows and exterior doors open to outside areas that are free of people, open the windows and exterior doors to dilute the vapor concentrations in the room. Prevent access to the area by putting up signs and, if necessary, seeking help from other staff persons, and then leave the area to prepare for cleanup.

7. Prepare for cleanup: Remove jewelry, watch, mobile phones, and other metal containing items. Get the mercury spill kit.

8. Put on personal protective equipment (PPE): Change to old clothes if possible. Put on the apron or coveralls, disposable shoe covers, rubber or nitrile gloves, goggles, and face mask before re-entering the spill site. Make sure metal items such as eyeglass frames are covered by PPE.

9. Remove visible mercury beads and broken glass: Place the jar and container on the plastic tray. Starting from the outside of the spill site and moving towards the center, carefully remove visible mercury beads and broken glass. Use tweezers to remove broken glass pieces and place them in the jar or wide-mouthed container over the tray. Using a playing card or piece of plastic, slide the mercury beads onto the plastic dustpan or scoop, and away from any carpet or porous surface. Use a slow, short, sweeping motion to prevent spreading mercury droplets. Carefully place the mercury beads into the plastic container partially filled with water or vapor suppression agent. Do this over the tray to catch any spillage. You can also use an eyedropper or syringe for small beads. Hold the eyedropper or syringe almost parallel to the floor to draw in the beads and keep the eyedropper or syringe horizontal when transferring the beads to the plastic container so as to prevent the mercury from falling out.

10. Search for and remove tiny mercury droplets and glass: Search for any remaining droplets and glass pieces by shining the flashlight at different low angles to the floor and looking for reflections from the shiny droplets and glass. For very tiny droplets, it may be easier to pick them up using sticky tape but be careful since they may not always stick. Place the sticky tape in the sealable plastic bag.

11. Clean up cracks and hard surfaces: Sprinkle sulfur powder on cracks and crevices, and on hard surfaces (tile, linoleum, wood, etc.) that had come in contact with mercury; a color change in the powder from yellow to reddish brown indicates that mercury is still present and more cleanup is needed. If so, sprinkle zinc flakes or copper flakes to amalgamate any residual mercury. Use the brush or small broom to remove the powder and/or the metal flakes and place them in the sealable plastic bag. An alternative way to clean hard surfaces after adding sulfur powder is to wipe them with vinegar soaked cotton swabs, followed by peroxide-soaked swabs. Place the swabs in a sealable plastic bag.

12. Remove contaminated soft materials: Carpets, carpet padding, upholstery, curtains, rugs, bedding, and other soft materials cannot be cleaned easily. Use the utility knife to cut out pieces of carpet, padding,

and other soft materials that are contaminated with mercury. Place the contaminated materials in a sealable plastic bag.

13. Clean out contaminated drains: If mercury was spilled over a drain, sink or wash basin, work with the facility engineer to remove and replace the "J", "U" or "S" trap. Put a sheet of plastic or plastic tray under the work area to catch any mercury that might spill out. Hold the old trap over a tray while transferring the mercury to the air-tight container. Dispose of the old trap as hazardous waste.

14. Dispose of or decontaminate cleanup material: Place all contaminated materials used during the cleanup (including cards, plastic pieces, cardboard, paper, rags, cotton swabs, paper towels, sticky tape, piece of soap, brush, or broom) into a leakproof, sealable plastic bag. Other items (tweezers, plastic scoop, tray, eyedropper, utility knife, etc.) should either be disposed with the contaminated items in the sealable plastic bag or cleaned thoroughly with the decontaminant solution.

15. Label and seal all contaminated material: Ensure that the air-tight jar and container are filled with enough water to cover the elemental mercury and broken glassware, close the jar and container tightly, label, and place each in a re-sealable plastic bag. The jar and container should be stored safely for future use. Place all sealed plastic bags with mercury-contaminated waste inside a second plastic bag, seal the outer bag using duct tape, and affix a label ("Mercury: Hazardous waste" or as directed by local authorities) and include a brief description of the contents. The mercury waste can be stored temporarily on site.

16. Remove and dispose or decontaminate PPE: Remove PPE beginning with the shoe covers which should be placed in another sealable bag. Then remove the gloves by grasping one glove with the other, peeling off the first glove, sliding the fingers under the remaining glove at the wrist, peeling off the second glove, and discarding both gloves in the sealable plastic bag. Next, remove the goggles by the head band or ear pieces. Remove the apron or coverall without touching the front and turn inside out. Finally, remove the face mask or respirator without touching the front. Dispose of the gloves, shoe covers, apron (and regular face mask if used in lieu of a specialty mask) in the sealable plastic bag, which should be stored along with the mercury waste. Decontaminate goggles and respirators or specialty face mask using the decontaminant solution.

17. Wash hands and all exposed skin: Use soap and water to scrub all exposed skin and rinse thoroughly.

18. Ventilate the spill area: Place a fan next to the spill area to volatilize mercury and a second fan in a window or doorway to move air to the outside air for 48 hours or more. If this is not possible due to central heating or air conditioning, increase the air exchange rate for the building for several days to reduce any mercury vapor concentrations. NOTE: If more than the amount in one thermometer was spilled on a wood floor or other porous material, use heaters to heat the room to about 30o C while blowing the air to the outside.

19. Medical monitoring: If the spill resulted in acute exposure to a patient or health worker, conduct blood and urine tests, provide support for respiratory and cardiovascular function and, if necessary, initiate chelation therapy if the person is symptomatic of acute mercury poisoning.

20. Write a report on the spill incident: Document the incident in keeping with the procedures of the health facility. The report can be used to improve safety in the facility.

The following should not be done in the event of a spill:

- Do not use a regular vacuum cleaner to pick up the mercury and mercury-contaminated items. The mercury will become airborne by way of the vacuum's exhaust and spread the contamination. Moreover, the vacuum cleaner will become contaminated and would have to be disposed as hazardous waste.

- Do not wash mercury-contaminated clothing, rugs or other fabrics in a washing machine. The washing machine and wastewater may become contaminated.

- Do not use a broom to sweep up the mercury. It can break the mercury into smaller beads, spreading them.

- Do not pour mercury down the drain. You may contaminate your plumbing, septic system, or your local sewage treatment plant.

- Do not spread mercury that has gotten onto your shoes. If possible, clean the shoes with the decontaminant solution. If the shoes cannot be decontaminated, wrap them in a plastic bag and dispose of them properly.

ANNEX D. Sample Material Safety Data Sheet for Mercury[59]

Mercury

ACC# 14020

Section 1 - Chemical Product and Company Identification

MSDS Name: Mercury
Catalog Numbers: 13-410, 13-411, 13-480, 13-481, 13-482, 13-485, 13501, M139-1LB, M139-5LB, M140-14LB, M140-1LB, M140-5LB, M141-1LB, M141-6LB
Synonyms: Colloidal mercury; Hydrargyrum; Metallic mercury; Quick silver; Liquid silver.
Company Identification:
Fisher Scientific
1 Reagent Lane
Fair Lawn, NJ 07410
For information, call: 201-796-7100
Emergency Number: 201-796-7100
For CHEMTREC assistance, call: 800-424-9300
For International CHEMTREC assistance, call: 703-527-3887

Section 2 - Composition, Information on Ingredients

CAS#	Chemical Name	Percent	EINECS/ELINCS
7439-97-6	Mercury	100	231-106-7

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Appearance: silver liquid.
Danger! Causes irritation and possible burns by all routes of exposure. Corrosive. Harmful if inhaled. May be absorbed through intact skin. May cause central nervous system effects. This substance has caused adverse reproductive and fetal effects in animals. Inhalation of fumes may cause metal-fume fever. May cause liver and kidney damage. Possible sensitizer.
Target Organs: Blood, kidneys, central nervous system, liver, brain.

Potential Health Effects
Eye: Exposure to mercury or mercury compounds can cause discoloration on the front surface of the lens, which does not interfere with vision. Causes eye irritation and possible burns. Contact with mercury or mercury compounds can cause ulceration of the conjunctiva and cornea.
Skin: May be absorbed through the skin in harmful amounts. May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material. Causes skin irritation and possible burns. May cause skin rash (in milder cases), and cold and clammy skin with cyanosis or pale color.
Ingestion: May cause severe and permanent damage to the digestive tract. May cause perforation of the digestive tract. May cause effects similar to those for inhalation exposure. May cause systemic effects.

59 Ibid. 11

Inhalation: Causes chemical burns to the respiratory tract. Inhalation of fumes may cause metal fume fever, which is characterized by flu-like symptoms with metallic taste, fever, chills, cough, weakness, chest pain, muscle pain and increased white blood cell count. May cause central nervous system effects including vertigo, anxiety, depression, muscle incoordination, and emotional instability. Aspiration may lead to pulmonary edema. May cause systemic effects. May cause respiratory sensitization.
Chronic: May cause liver and kidney damage. May cause reproductive and fetal effects. Effects may be delayed. Chronic exposure to mercury may cause permanent central nervous system damage, fatigue, weight loss, tremors, personality changes. Chronic ingestion may cause accumulation of mercury in body tissues. Prolonged or repeated exposure may cause inflammation of the mouth and gums, excessive salivation, and loosening of the teeth.

Section 4 - First Aid Measures

Eyes: Get medical aid immediately. Do NOT allow victim to rub eyes or keep eyes closed. Extensive irrigation with water is required (at least 30 minutes).
Skin: Get medical aid immediately. Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Destroy contaminated shoes.
Ingestion: Do not induce vomiting. If victim is conscious and alert, give 2-4 cupfuls of milk or water. Never give anything by mouth to an unconscious person. Get medical aid immediately. Wash mouth out with water.
Inhalation: Get medical aid immediately. Remove from exposure and move to fresh air immediately. If breathing is difficult, give oxygen. Do NOT use mouth-to-mouth resuscitation. If breathing has ceased apply artificial respiration using oxygen and a suitable mechanical device such as a bag and a mask.
Notes to Physician: The concentration of mercury in whole blood is a reasonable measure of the body-burden of mercury and thus is used for monitoring purposes. Treat symptomatically and supportively. Persons with kidney disease, chronic respiratory disease, liver disease, or skin disease may be at increased risk from exposure to this substance.
Antidote: The use of d-Penicillamine as a chelating agent should be determined by qualified medical personnel. The use of Dimercaprol or BAL (British Anti-Lewisite) as a chelating agent should be determined by qualified medical personnel.

Section 5 - Fire Fighting Measures

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Water runoff can cause environmental damage. Dike and collect water used to fight fire. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.
Extinguishing Media: Substance is nonflammable; use agent most appropriate to extinguish surrounding fire. Use water spray, dry chemical, carbon dioxide, or appropriate foam.
Flash Point: Not applicable.
Autoignition Temperature: Not applicable.
Explosion Limits, Lower: Not available.
Upper: Not available.
NFPA Rating: (estimated) Health: 3; Flammability: 0; Instability: 0

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.
Spills/Leaks: Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Avoid runoff into storm sewers and ditches which lead to waterways. Clean up spills immediately, observing precautions in the Protective Equipment section. Provide ventilation.

Section 7 - Handling and Storage

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Minimize dust generation and accumulation. Keep container tightly closed. Do not get on skin or in eyes. Do not ingest or inhale. Use only in a chemical fume hood. Discard contaminated shoes. Do not breathe vapor.
Storage: Keep container closed when not in use. Store in a tightly closed container. Store in a cool, dry, well-ventilated area away from incompatible substances. Keep away from metals. Store protected from azides.

Section 8 - Exposure Controls, Personal Protection

Chemical Name	ACGIH	NIOSH	OSHA - Final PELs
Mercury	▪ 0.025 mg/m3 TWA; Skin - potential significant contribution to overall exposure by the cutaneous r oute	0.05 mg/m3 TWA (vapor) 10 mg/m3 IDLH	0.1 mg/m3 Ceiling

Engineering Controls: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use only under a chemical fume hood.
Exposure Limits

OSHA Vacated PELs: Mercury: 0.05 mg/m3 TWA (vapor)
Personal Protective Equipment
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin: Wear appropriate protective gloves to prevent skin exposure.
Clothing: Wear appropriate protective clothing to prevent skin exposure.
Respirators: A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

Section 9 - Physical and Chemical Properties

Physical State: Liquid
Appearance: silver
Odor: odorless
pH: Not available.
Vapor Pressure: 0.002 mm Hg @ 25C
Vapor Density: 7.0
Evaporation Rate: Not available.
Viscosity: 15.5 mP @ 25 deg C
Boiling Point: 356.72 deg C
Freezing/Melting Point:-38.87 deg C
Decomposition Temperature: Not available.
Solubility: Insoluble.
Specific Gravity/Density:13.59 (water=1)
Molecular Formula: Hg
Molecular Weight:200.59

Section 10 - Stability and Reactivity

Chemical Stability: Stable under normal temperatures and pressures.
Conditions to Avoid: High temperatures, incompatible materials.
Incompatibilities with Other Materials: Oxygen, sulfur, acetylene, ammonia, chlorine dioxide, azides, chlorates, nitrates, sulfuric acid, halogens, rubidium, calcium, 3-bromopropyne, ethylene oxide, lithium, methylsilane + oxygen, peroxyformic acid, tetracarbonylnickel + oxygen, copper, copper alloys, boron diiodophosphide, metals, nitromethane, sodium carbide, aluminum, lead, iron, metal oxides.
Hazardous Decomposition Products: Mercury/mercury oxides.
Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

RTECS#:
CAS# 7439-97-6: OV4550000
LD50/LC50:
Not available.

Carcinogenicity:
CAS# 7439-97-6: Not listed by ACGIH, IARC, NTP, or CA Prop 65.

Epidemiology: Intraperitoneal, rat: TDLo = 400 mg/kg/14D-I (Tumorigenic - equivocal tumorigenic agent by RTECS criteria - tumors at site of application).
Teratogenicity: Inhalation, rat: TCLo = 1 mg/m3/24H (female 1-20 day(s) after conception) Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus).
Reproductive Effects: Inhalation, rat: TCLo = 890 ng/m3/24H (male 16 week(s) pre-mating) Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count).; Inhalation, rat: TCLo

= 7440 ng/m3/24H (male 16 week(s) pre-mating) Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants).
Mutagenicity: Cytogenetic Analysis: Unreported, man = 150 ug/m3.
Neurotoxicity: The brain is the critical organ in humans for chronic vapor exposure; in severe cases, spontaneous degeneration of the brain cortex can occur as a late sequela to past exposure.
Other Studies:

Section 12 - Ecological Information

Ecotoxicity: Fish: Rainbow trout: LC50 = 0.16-0.90 mg/L; 96 Hr; UnspecifiedFish: Bluegill/Sunfish: LC50 = 0.16-0.90 mg/L; 96 Hr; UnspecifiedFish: Channel catfish: LC50 = 0.35 mg/L; 96 Hr; UnspecifiedWater flea Daphnia: EC50 = 0.01 mg/L; 48 Hr; Unspecified In aquatic systems, mercury appears to bind to dissolved matter or fine particulates, while the transport of mercury bound to dust particles in the atmosphere or bed sediment particles in rivers and lakes is generally less substantial. The conversion, in aquatic environments, of inorganic mercury cmpd to methyl mercury implies that recycling of mercury from sediment to water to air and back could be a rapid process.
Environmental: Mercury bioaccumulates and concentrates in food chain (concentration may be as much as 10,000 times that of water). Bioconcentration factors of 63,000 for freshwater fish and 10,000 for salt water fish have been found. Much of the mercury deposited on land, appears to revaporize within a day or two, at least in areas substantially heated by sunlight.
Physical: All forms of mercury (Hg) (metal, vapor, inorganic, or organic) are converted to methyl mercury. Inorganic forms are converted by microbial action in the atmosphere to methyl mercury.
Other: No information available.

Section 13 - Disposal Considerations

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.
RCRA P-Series: None listed.
RCRA U-Series:
CAS# 7439-97-6: waste number U151.

Section 14 - Transport Information

	US DOT	Canada TDG
Shipping Name:	MERCURY	MERCURY
Hazard Class:	8	8
UN Number:	UN2809	UN2809
Packing Group:	III	III

Section 15 - Regulatory Information

US FEDERAL

TSCA

CAS# 7439-97-6 is listed on the TSCA inventory.

Health & Safety Reporting List

None of the chemicals are on the Health & Safety Reporting List.

Chemical Test Rules

None of the chemicals in this product are under a Chemical Test Rule.

Section 12b

CAS# 7439-97-6: Section 5, 1 % de minimus concentration

TSCA Significant New Use Rule

CAS# 7439-97-6: This product is for research and development use only. It is subject to a SNUR which has specific requirements and restrictions. The specific citation for this product is 4040 CFR 721.10068.

CERCLA Hazardous Substances and corresponding RQs

CAS# 7439-97-6: 1 lb final RQ; 0.454 kg final RQ

SARA Section 302 Extremely Hazardous Substances

None of the chemicals in this product have a TPQ.

SARA Codes

CAS # 7439-97-6: immediate, delayed.

Section 313

This material contains Mercury (CAS# 7439-97-6, 100%),which is subject to the reporting requirements of Section 313 of SARA Title III and 40 CFR Part 373.

Clean Air Act:

CAS# 7439-97-6 (listed as Mercury compounds) is listed as a hazardous air pollutant (HAP).

This material does not contain any Class 1 Ozone depletors.

This material does not contain any Class 2 Ozone depletors.

Clean Water Act:

None of the chemicals in this product are listed as Hazardous Substances under the CWA. CAS# 7439-97-6 is listed as a Priority Pollutant under the Clean Water Act. CAS# 7439-97-6 is listed as a Toxic Pollutant under the Clean Water Act.

OSHA:

None of the chemicals in this product are considered highly hazardous by OSHA.

STATE

CAS# 7439-97-6 can be found on the following state right to know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California Prop 65

WARNING: This product contains Mercury, a chemical known to the state of California to cause developmental reproductive toxicity.

California No Significant Risk Level: None of the chemicals in this product are listed.

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols:

T N

Risk Phrases:

R 23 Toxic by inhalation.

R 33 Danger of cumulative effects.
R 50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety Phrases:

S 1/2 Keep locked up and out of reach of children.
S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S 7 Keep container tightly closed.
S 60 This material and its container must be disposed of as hazardou s waste.
S 61 Avoid release to the environment. Refer to special instructions /safety data sheets.

WGK (Water Danger/Protection)

CAS# 7439-97-6: 3

Canada - DSL/NDSL

CAS# 7439-97-6 is listed on Canada's DSL List.

Canada - WHMIS

This product has a WHMIS classification of D2A, E.

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

Canadian Ingredient Disclosure List

CAS# 7439-97-6 is listed on the Canadian Ingredient Disclosure List.

Section 16 - Additional Information

MSDS Creation Date: 6/15/1999

Revision #10 Date: 1/13/2009

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall Fisher be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Fisher has been advised of the possibility of such damages.