

Developing national strategies for

PHASING OUT MERCURY-CONTAINING

thermometers and sphygmomanometers in health care,
including in the context of the Minamata Convention on Mercury



KEY CONSIDERATIONS AND STEP-BY-STEP GUIDANCE



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

Developing national strategies for phasing out mercury-containing thermometers and sphygmomanometers in health care, including in the context of the Minamata Convention on Mercury: key considerations and step-by-step guidance.

1.Sphygmomanometers - standards. 2.Thermometers - standards. 3.Mercury - adverse effects. 4.Monitoring, Physiologic - instrumentation. 5.Environmental Exposure. 6.National Health Programs. I.World Health Organization.

ISBN 978 92 4 150833 9

(NLM classification: QV 293)

© World Health Organization 2015

All rights reserved. Publications of the World Health Organization are available on the WHO website (www.who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: bookorders@who.int).

Requests for permission to reproduce or translate WHO publications –whether for sale or for non-commercial distribution– should be addressed to WHO Press through the WHO website (www.who.int/about/licensing/copyright_form/en/index.html).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Photo from HCWH/Faye Ferrer.

Design and layout by Mitzi Damazo-Sabando.

Printed in Switzerland.

Developing national strategies for
**phasing out mercury-containing
thermometers and sphygmomanometers in health care,**
including in the context of the Minamata Convention on Mercury

KEY CONSIDERATIONS AND STEP-BY-STEP GUIDANCE



Contents

Foreword	iv
Acknowledgements	v
Acronyms and abbreviations	vi
Introduction	1
Linkages with the Minamata Convention on Mercury	2
Model process for developing a health system-wide strategy to phase out mercury-containing measuring devices	3
I. Development of a stakeholder engagement strategy	4
II. Situation assessment and inventory	5
III. Strategy development and implementation	7
IV. Monitoring and reporting	11
References	12
Annotated bibliography	13

Foreword

Mercury is a naturally occurring heavy metal which has been used since ancient times. It is also a significant health hazard.

Mercury vapour, when inhaled, can affect the central nervous system and, depending on exposure levels, can impair cognition and in some cases cause death. Mercury is also harmful if absorbed through cuts and abrasions of the skin. Of even more concern in terms of public health is the toxicity produced when mercury emitted into the environment accumulates in lake, river, stream and ocean sediments. There, anaerobic organisms digest and transform it into methyl mercury, a more toxic form of mercury which accumulates and becomes concentrated up the food chain in plankton, fish, birds and mammals including humans. Methyl mercury is of special concern for fetuses, infants and children because extraordinarily low doses impair neurological development.

Exposure to elemental mercury in health care settings from spills or broken equipment, such as mercury-containing fever thermometers and sphygmomanometers (blood pressure devices), is a serious health problem for employees, patients and visitors as well as those tasked with repairing and cleaning up such broken equipment. It is also a problem that is entirely preventable through the careful choice and use of mercury-free alternatives.

Many hospitals and health facilities, including those participating in WHO and Health Care Without Harm collaborative efforts to promote mercury-free health care, have already successfully switched to mercury-free thermometers and sphygmomanometers. A number of governments representing low-, middle- and high-income countries have also instituted policies for phasing out such devices in favour of accurate and affordable alternatives.

By signing of the Minamata Convention on Mercury in Kumamoto, Japan in October 2013, governments made a commitment to protect human health from anthropogenic emissions and releases of mercury and mercury compounds. The role of ministries of public health and WHO in supporting the implementation of the Convention, including actions to be taken within the health sector, was further affirmed by the Sixty-seventh World Health Assembly in resolution WHA67.11.¹ The Convention sets a phase-out date of 2020 for the manufacture, import and export of mercury thermometers and sphygmomanometers. This guidance provides advice to health ministries on the leading role they will need to take in this regard.



Maria Neira

Director

Department of Public Health, Environmental and Social Determinants of Health

WHO

¹ Section 2 (3) of Resolution WHA67.11 calls upon Member States to address the health aspects of exposure to mercury and mercury compounds in the context of their health sector uses, and also the other negative health impacts that should be prevented or treated, by ensuring the sound management of mercury and mercury compounds throughout their life cycle.

Acknowledgements

The World Health Organization wishes to express its appreciation to all whose efforts made the production of this publication possible.

A first draft of this publication was prepared at the request of the World Health Organization by Josh Karliner (Health Care Without Harm, United States of America), Susan Wilburn (Health Care Without Harm, United States of America)², and Peter Orris (University of Illinois School of Public Health, United States of America). It was then revised and finalized by the Secretariat under the direction of staff of the Department of Public Health, Environmental and Social Determinants of Health of WHO, including Ms Michaela Pfeiffer, Ms Carolyn Vickers, and Dr Carlos Dora.

The following individuals also contributed to the development of the publication as part of the peer review: Ana Boischio (Pan-American Health Organization, United States of America), Jorge Emmanuel (UNDP-GEF Global Health Care Waste Project, United States of America), Rico Euripidou (groundWork, South Africa), Jan-Gerd Kuehling (ETLog Health EnviroTech and Logistics GmbH, Germany), Irma Makalinao (University of the Philippines, Philippines), Megha Rathi (Consultant to World Health Organization, Switzerland), Vital Ribiero (Projeto Hospitais Saudáveis, Brazil), Ernesto di Titto (Ministry of Health, Argentina).

Financial support provided for this publication by the German Federal Ministry of the Environment, Nature Conservation, Building and Nuclear Safety is gratefully acknowledged.

² A former WHO staff member who also provided technical leadership and input into the initial development of this document.

Acronyms and abbreviations

EC	European Commission
EU	European Union
GEF	Global Environment Facility
HCWH	Health Care Without Harm
MIA	Minamata Initial Assessment
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
WHA	World Health Assembly
WHO	World Health Organization

Introduction

With the adoption of the Minamata Convention on Mercury in October 2013, clear time-bound targets were set for phasing out the manufacture, export or import of a number of mercury-added products specified in the Convention. For thermometers and sphygmomanometers that are included in a wider category of non-electronic medical devices regulated under Article 4 of the Convention, the phase-out date is 2020, with the possibility of Party-specific exemptions up to 2030. An open-ended exemption is also afforded to products for research, calibration of instrumentation, and for use as a reference standard.

The implications of the provisions of Article 4 are that Parties may not procure mercury-containing thermometers or sphygmomanometers after 2020 (or 2030 for Parties afforded the maximum exemptions) for routine use in health care settings. Replacement of these devices with mercury-free alternatives will thus become a necessity when they reach their end-of-service life.

Many mercury-free thermometers and sphygmomanometers are available which provide equivalent accuracy and comparable clinical utility (1).

Many examples of successful substitution programmes exist, demonstrating that it is possible and affordable to switch to mercury-free alternatives. Much of this work has been done in the context of movements driven by health-care-providers to promote mercury-free health care. For example, WHO and Health Care Without Harm collaborate in order to promote mercury-free health care, key aims being to raise awareness about environmental and health risks associated with the use of mercury-containing medical measuring devices, and to provide technical and policy guidance in support of the switch to mercury-free alternatives. These efforts have been critical in developing and documenting good practice examples and demonstrating the feasibility of implementing voluntary replacement (at end-of-service life) and substitution (prior to end-of-service life) programmes.

This publication was developed to guide health ministries in planning and leading the development of national strategies to phase out mercury-containing thermometers and sphygmomanometers in health care, including through substitution and replacement with alternatives.

It is recognized that the approach taken will need to be adapted to each country's needs. Thus the measures suggested in this guidance are intended to inform health ministries and partners involved in these efforts about key considerations to be taken into account at each point in the process. Sample activities and objectives are highlighted, as are issues that may require more in-depth consideration. An indication of technical resources available and good practice examples are also provided.

The publication focuses primarily on national or country-wide strategies and programmes targeted to health care facilities and settings, both public and private. Some reference is made to sub-national and facility level considerations as relevant. While there are many potential sources of mercury in health care settings (for example, fluorescent lamps, canton tubes, dilators, mercury switches, some button batteries and dental amalgam), this guide specifically addresses the phase out of mercury-containing thermometers and sphygmomanometers. By adopting the use of mercury-free thermometers and sphygmomanometers, health care facilities can make a significant contribution to reducing mercury emissions while simultaneously reducing exposure of patients and staff.

Linkages with the Minamata Convention on Mercury

The protection of human health is at the core of the Minamata Convention, whose objective (Article 1) “is to protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds”.³

The Convention includes a range of measures to meet its objective, including controls on emissions and releases of mercury to the environment from industrial sources and the phasing out of the manufacture, import or export of certain products or product components that contain mercury or a mercury compound that was intentionally added (“mercury-added products”). One mercury-added product (dental amalgam) is subject to a phase down in use.

The Convention includes an article dedicated to health aspects (Article 16) which specifically calls for the development and implementation of strategies and programmes to protect populations at risk from exposure to mercury and mercury compounds, including through the adoption of national guidelines and through health promotion and public education. This Article also calls for the promotion of preventive and curative health services for persons affected by exposure to mercury and the strengthening of health sector capacities for addressing mercury-related health issues.

Involvement of health ministries is indicated in order to develop the required public health strategy element of national action plans to reduce the health impacts of mercury use in artisanal and small-scale gold mining (Article 7 and Annex C) as well as for assessing the risks to health of contaminated sites (Article 12). Article 17 on information exchange specifically mentions information on health impacts.

Article 18 on public information, awareness and education particularly mentions human health, while Article 19 (Research, development and monitoring) calls for cooperation in assessing the impact of mercury and mercury compounds on vulnerable populations.

Actions addressed in this guide relate specifically to Article 4 of the Convention which addresses mercury-added products. Mercury-containing measuring devices, including thermometers and sphygmomanometers, are among the items listed whose manufacture, import and export must cease by 2020, except where exemptions apply.⁴

³ For full Convention text, see <http://www.mercuryconvention.org/Convention/tabid/3426/Default.aspx>, accessed 24 September 2014.

⁴ See Annex A of the Convention for details of products subject to the requirements under Article 4.

Model process for developing a health system-wide strategy to phase out mercury-containing measuring devices

As indicated earlier, it is understood that countries will design and implement approaches to phasing out mercury-containing measuring devices in ways most suited to their particular needs and context. That said, there are some common steps that ideally would form part of this process. These are summarized in Fig. 1.

Fig.1. Summary overview of key steps in developing and implementing a national health system-wide strategy

STEP/PHASE	DESIRED OUTCOMES
I. Development of a stakeholder engagement strategy	<ul style="list-style-type: none"> • Definition of management and oversight arrangements for the development and implementation of the strategy and interventions • Identification of those stakeholder groups needed to support the roll-out of the initiative • Establishment of process for engaging stakeholders (several of whom may not be the same) as part of strategy development and implementation
II. Situation assessment and inventory	<ul style="list-style-type: none"> • Identification of number/quantity of medical devices requiring replacement or substitution • Assessment of availability of alternative mercury-free devices and related supporting services e.g. maintenance, validation, calibration • Definition of volume of waste material to be collected, stored and disposed of • Assessment of available/existing capacity to support phase-out activities and identification of gaps, including for safe collection, storage, and environmentally sound disposal • Identification of priority areas (e.g. locations, facilities) to be targeted for initial interventions and activities • Estimation of costs associated with potential phase-out scenarios • Formulation of recommendations on available options for implementation of phase-out activities
III. Strategy development and implementation	<ul style="list-style-type: none"> • Definition of specific intervention packages and supporting activities, agreed by all partners/stakeholders • Agreement reached on roles and responsibilities for delivery of the above in relation to time-bound targets and measurable indicators • Establishment of monitoring framework to facilitate reporting on delivery of interventions and any unforeseen or unexpected issues/impacts
IV. Monitoring and reporting	<ul style="list-style-type: none"> • Monitoring of results of interventions and supporting activities with subsequent reporting to designated officer/entity responsible for execution of the strategy; • Adjustment of strategic approach as needed and in agreement with partners/stakeholders, taking into consideration lessons learned • Detection and reporting, as relevant, of unforeseen issues/impacts related to the implementation of measures under the strategy

In the sections that follow, a more detailed overview of the types of activities that would normally be undertaken during each of the above steps is provided. Key issues to be taken into considerations are also highlighted.

While Fig. 1 provides a linear image of the process, it is in reality a much more iterative process, where information and feedback generated as a result of monitoring and reporting activities are used to inform and adjust the strategy and programme of activities as needed. Similarly, stakeholder engagement activities would occur at all stages of the process.

I. Development of a stakeholder engagement strategy

Stakeholder engagement is critical to the success of the overall strategy and should begin at the earliest point possible. The extent to which the process is seen to be inclusive of the views and inputs of all relevant actors can influence the extent to which those actors feel ownership and responsibility for the delivery of specific interventions. For example, transparency and accountability in the design of interventions and allocation of resources can be strengthened through stakeholder engagement and information disclosure. This can be important in contexts where there is significant external concern or resistance to these activities.

While the health sector will have a leading role to play in developing and implementing a phase-out strategy for mercury-containing medical devices used in health care, contributions from other sectors and actors will also be needed in order to support strategy development and implementation.

Stakeholder groups would include:

- regulatory authorities within the respective line ministries (for example, health, environment, labour, industry) that would have responsibility for the development and enforcement of policies and standards related to procurement, use, storage, handling and environmentally sound disposal⁵ of mercury-containing medical devices, as well as any substitute products or devices. Such authorities include regulatory agencies or authorities responsible for registry, trade and certification of mercury- and non-mercury-containing medical devices;
- suppliers and manufacturers of mercury-containing and mercury-free thermometers and sphygmomanometers, with whom engagement is necessary to ensure adequate availability, affordability and maintenance of products as well as clinical validation and conformity with national requirements;
- hospital associations and managers of major health care facilities in both the public and private sectors;
- public and private associations of health professionals (for example, national organizations of doctors and nurses, a national public health association, national society of hypertension) which could provide expertise and support the wider health sector effort by incorporating the use of mercury-free medical devices in their technical guidelines;
- clinicians/medical doctors, nurses, other health care providers who would be the primary users of mercury-free devices and would have a key role in changing the type of devices procured and used;
- managers of facilities and individuals such as janitors, refuse workers and their organizations who would be responsible for handling, storing, treating and disposing of mercury-containing wastes;
- researchers from academia or national institutions who would probably be directly or indirectly involved in one or more supporting activities such as conducting or contributing to situation assessments, supporting clinical evaluations of the health impacts of mercury exposure, developing standards and test protocols for new devices, contributing to monitoring and reporting

⁵ Improper disposal of mercury-containing wastes can result in releases of mercury. Annex IV of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (see Annex) and UNEP's "Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and waste containing or contaminated with mercury" specify environmentally sound disposal operations, including stabilization and solidification processes followed by disposal in specially engineered landfills or permanent underground storage facilities. In this context, environmentally sound disposal requires planning, infrastructure, careful site selection, specific technologies, specialized design and construction, and continuous monitoring all of which countries and regions may have to develop over time.

efforts, and developing and teaching course curricula for health professionals;

- civil society or nongovernmental organizations which have been active in promoting environmental sustainability and/or occupational health and safety in the health sector, international organizations providing health care, etc.

The task of developing a stakeholder engagement strategy (which would be an integral component of the overall strategy) would likely be incumbent upon the ministry of health representative(s) charged with overseeing the development and delivery of phase-out activities in the health sector.

Key considerations related to stakeholder engagement

The stakeholder engagement strategy should:

- be informed by a thorough stakeholder mapping, ideally through a participatory process which has identified all relevant details about each stakeholder's role, interests and potential influence over the process;
- include details about which kinds of participatory instruments, methods and processes (workshops, key informant interviews, focus group discussions, town hall meetings, etc.) will be used at which points in the process in order to facilitate and ensure adequate stakeholder involvement;
- address the stakeholder engagement needed to support the development of the overall phase out strategy and to support its implementation including any related monitoring, reporting and enforcement activities. It should be noted that these groups and the balance of their composition may be different.

II. Situation assessment and inventory of mercury-containing measuring devices

This is a critical step in the development of the overall strategy. It is necessary in order to clarify and define the scope of work required to achieve the 2020 targets applicable to these devices. It will also set a baseline against which progress made in achieving the targets can and will be measured.

The situation assessment and inventory should:

- gauge the feasibility of replacement or substitution of devices with mercury-free alternatives, including determining if products are locally available, cost competitive, and meet minimum international standards. The availability of maintenance, validation and calibration services, including replacement parts as applicable should also be considered;
- determine the number of devices to be replaced or substituted;
- identify relevant national regulations and requirements as well as possible gaps or areas that would require strengthening or further clarification as part of phase-out activities. For example, it may be necessary to include additional provisions in existing health care waste management regulations in order to address the safe and environmentally sound storage, handling and disposal of mercury-containing medical measuring devices as well as mercury-free products introduced as replacements;
- assess existing capacities, procedures, and facilities for safe storage, transport and disposal of mercury-added devices at all levels of the health system, including in the context of existing national, sub-national and municipal health care waste management systems as relevant; assess existing capacities and infrastructure for testing, evaluation, certification, repair and maintenance of non-mercury thermometers and sphygmomanometers;
- identify priority areas and facilities where initial activities or interventions should be directed. For

example, priority could be determined based on the stature and influence of a facility (i.e., its ability to encourage good practices in other health facilities). Priority could also be given to facilities based on their degree of mercury use and/or health impact (paediatric hospitals, maternity clinics, etc.).

Key considerations related to the situation assessment

- To the extent feasible, the situation assessment should take into account and seek to quantify the number of mercury-containing measuring devices in use and in stock at all levels of the health care system, both public and private.
- Existing policies and practices related to handling, storage and disposal of mercury-containing products in health care facilities should be considered so as to identify existing structures and procedures that can be utilized for phase-out activities, and to identify gaps and areas where further support for capacity building may be warranted.
- Available data and evidence should be gathered the rate and frequency of breakage of mercury-containing measuring devices. This will be important later for estimating the time frame within which alternative products will need to be provided. Gathering data on mercury exposure in health care will also be useful in demonstrating health benefits as well as cost savings associated with a switch to mercury-free measuring devices, in particular digital thermometers which tend to break less often and therefore have a lower replacement cost than mercury-containing thermometers.
- Knowledge, attitudes, practices and beliefs of health care practitioners should be taken into consideration when designing the awareness-raising and capacity-building efforts that will be needed at the start of phase-out activities. For example, in order to promote a change in practice, it may be necessary to address the perceptions of device users regarding the clinical accuracy and reliability of non-mercury thermometers and sphygmomanometers.
- Current purchasing and procurement policies, structures, and patterns should be considered.
- Cost should be an element of situation assessment where different options are under consideration, such as replacement only at end-of-service life or strategies for substitution prior to end-of-service life.
- If possible, the situation assessment and mercury medical device inventory should be aligned with other national activities related to the implementation of the Minamata Convention. Box 1 provides a description of the Minamata Initial Assessment process and related financing opportunities available through the Global Environment Facility Trust Fund for conducting the situation assessment and inventory.

Box 1. Linking the situation assessment with other sector activities aimed at facilitating ratification of the Minamata Convention on Mercury

In line with Article 13 of the Convention, the Global Environment Facility Trust Fund provides financing in order to support the implementation of agreed commitments of the Convention. In an effort to facilitate the early entry into force of the Convention, a special grant mechanism called the Minamata Initial Assessment (MIA) was created. The objectives of the Assessment are to support activities that can enable countries to determine what is needed in order to ratify the Convention, and subsequently to provide a basis for further work towards implementation. One key activity to be conducted under the MIA is an initial mercury inventory

assessment. This considers mercury stocks, import and export procedures, storage conditions, the supply of mercury in the country, sectors that use mercury and the amount used annually, and trade in mercury and mercury-containing compounds.

A situation assessment of mercury-containing medical devices could readily be integrated into an MIA-supported mercury inventory assessment.

Source: Global Environment Facility, 2013 (2)

III. Strategy development and implementation

Once the results of the situation assessment and recommendations have been validated as part of ongoing stakeholder consultations, a plan of work and package of interventions need to be developed.

Issues to be clarified and addressed as part of this step include:

- definition of specific measures and interventions at national, sub-national and facility levels, together with time-bound targets for implementation;
- roles and responsibilities of different stakeholders and actors involved in the delivery of interventions should be clearly defined and delineated. For example, in the event that capacity-building activities are included as a key intervention area, it may be worthwhile to request a specific institution such as a public health university or teaching hospital to support such activities. If institutional capacity to support these activities is limited, due consideration should then be given to building implementation capacity as part of execution of the overall strategy and related activities;
- the overall management structures needed to support actions to be taken at national, sub-national and facility levels should be clarified. For example, there may be value in establishing some form of intersectoral body (a national committee or working group) to assume overall responsibility for the development and implementation of the plan of work;
- the roles, responsibilities and resources (technical and financial) available and required in order to implement the strategy and plan of work in its entirety need to be clarified.

Illustrative list of intervention areas likely to be covered

- A. Establishment of a national policy or regulation related to phasing-out mercury containing thermometers and sphygmomanometers.** This is critical for ensuring that phase-out measures are sustainable. The national policy or regulation provides the mandate for all health care facilities in the country to introduce phase-out activities and should ensure, at a minimum, compliance with the requirements of the Minamata Convention. Some examples of such national policies and regulation are highlighted in Box 2.
- B. Development and issuance of guidelines** covering all aspects of procurement, use, safe handling, storage, treatment, and environmentally sound disposal of both mercury-containing and mercury-free devices. Topics to be covered might include:
 - procedures for safe clean-up of mercury spills and the safe handling and environmentally sound disposal of broken devices;
 - guidelines on environmentally sound and safe interim storage of mercury devices and waste on the premises of hospitals and other health care facilities;
 - guidelines on longer-term storage of mercury-containing measuring devices, including points of storage. Requirements for transport, labelling, and safe handling might also be specified;
 - if applicable, guidelines or procedures related to the reuse or recycling of mercury from medical measuring devices, taking into account and ensuring coherence with relevant environmental regulations;
 - guidelines related to the safe and environmentally sound disposal of mercury-containing measuring devices and related waste, taking into account relevant provisions of the Basel Convention, the Stockholm Convention on Persistent Organic Pollutants and their respective implementation guidelines as applicable.
- C. Development and updating of national product standards** for mercury-free thermometers and sphygmomanometers. These product standards should be integrated into national, sub-national and facility procurement policies and requirements. Provisions also should be made to

Box 2. Sample national and regional policies and regulations established in support of phasing out mercury-containing measuring devices in health care.*

■ ARGENTINA

In February 2009, the Ministry of Health issued Resolution 139/2009 ending the purchase of new mercury medical devices in all the country's hospitals. This Resolution also established policy and procurement guidelines for the phase-out of thermometers and sphygmomanometers. In February 2010, the Ministry issued Resolution 274/2010 banning the production, import, sale or free transfer of mercury sphygmomanometers destined for use by the general public, medical doctors or veterinarians. The Resolution set a limit of 90 days in which to end production and 180 days to end any commercialization of these products.

■ CHILE

In April 2011, the Ministry of Health issued national guidance for Mercury-free Health Care. This requires that all institutions conduct mercury inventories, develop mercury spill management policies and begin a progressive transition to digital thermometers and sphygmomanometers by the end of 2011.

■ PHILIPPINES

In 2008, the Department of Health issued Administrative Order 21 calling for the phase-out of mercury-based medical devices across the country within two years. In December 2010, the Department of Interior and Local Government (DILG) issued Memorandum Circular 2010-140 enjoining all provincial governors, city and municipal mayors, DILG regional directors and others concerned to ensure compliance with the Department of Health's Administrative Order 21.

■ EUROPEAN UNION

In December 2006, the marketing of measuring devices containing mercury for use by the general public was restricted by Commission Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). In 2012, Commission (EU) Regulation No 847/2012 required that mercury sphygmomanometers and other measuring devices used for industrial and professional purposes be taken off the market as from April 2014.

Sources: Health Care Without Harm (3); European Commission (4)

*These examples predate the Minamata Convention. This guide makes no assessment of their adequacy in meeting Convention obligations.

monitor and ensure that mercury-free devices, whether produced or imported, comply with national safety and quality standards.

For products that are new to the country and have not yet been examined in light of regulatory or legislative requirements, it may be necessary to build national capacity for testing, evaluating, and certifying non-mercury devices. This can generally be done in collaboration with the national institute or agency in charge of technology standards, testing and certification.

D. Development of a collection and disposal strategy

for mercury-containing thermometers and sphygmomanometers. This should clearly articulate how such devices and related residues should be collected, handled, stored, transported and disposed of. Mechanisms for engagement with other responsible authorities such as ministries of environment and environmental protection agencies responsible for mercury, should also be defined. Guidance or procedures related to the transport and environmentally sound disposal of mercury-containing wastes from health care should be coordinated with

current or future national and regional plans for the final disposal of mercury and mercury-containing wastes. The cost implications of collection and disposal activities, including actions to be taken by individual facilities, should be estimated and form part of the plans developed to support implementation of the strategy.

E. Development of awareness-raising, training and capacity-building activities to support behaviour change, particularly among medical doctors, nurses and other health care providers, janitors, refuse workers, and their organizations who will be most directly affected by phasing-out activities. Acceptance of safe and appropriate use and maintenance of alternative devices will need to be ensured.

Such activities would need to be supported by the development and provision of guidance documents, training materials and practical training for procurement officers, waste handlers, hospital workers and health professionals concerning the health impacts of mercury and substitution of mercury thermometers and sphygmomanometers. Training on the health and safety considerations associated with clean-up of spills and handling of broken devices should also be included,

particularly as breakage can occur during collection and substitution activities. Furthermore, raising awareness about how to deal with a mercury thermometer breakage will help to reveal the costs associated with continued use of mercury thermometers (costs associated with proper clean-up and disposal measures).

Skill-based training on the use of new mercury-free equipment should be provided to all health workers and device users prior to distribution. This will help to foster greater awareness and commitment to the process.

F. Availability of affordable alternatives will need to be ensured by requiring medical device suppliers, local manufacturers, importers, international vendors, distributors, and purchasing organizations to make non-mercury devices available in the country. This may involve providing incentives and fostering competition in order to keep the costs of alternatives at an affordable level. It might also involve consideration of lowering import duties and taxes on mercury-free alternative measuring devices so as to facilitate more rapid entry of these products into the domestic market.

Box 3 provides some examples of the cost implications of phase-out activities.

Box 3. Sample economic considerations

Cost is a common concern cited in relation to the replacement and substitution of mercury-containing measuring devices. While the costs of a single mercury thermometer are far less than a digital device, such thermometers break far more frequently than the alternatives. In one of many examples, the National Institute of Traumatology and Orthopaedics in Rio de Janeiro, Brazil saved 33% of its outlay for thermometers by phasing out mercury devices (5).

	Time Period	Average Consumption	Cost Per Unit	Total Cost
Mercury thermometers	March 2010- March 2011	1700	US\$ 0.57	US\$ 969
Digital thermometers	April 2011- April 2012	250	US\$ 2.58	US\$ 645
TOTAL SAVINGS				US\$ 324

Sources: Health Care Without Harm (3); World Health Organization (1)

Similar findings can be cited from other countries. For example, at the Federico Gómez Children's Hospital of Mexico, it was estimated that this 250-bed institution would save US\$10 000 over six years if it switched to digital thermometers. Included in this estimate was the cost of replacement batteries as well as waste disposal.

In the 116-bed Hospital São Luiz in São Paulo, Brazil it was estimated that if all its wall and clinical thermometers and sphygmomanometers were to be replaced with mercury-free alternatives, the savings on maintenance and calibration would cover the initial investment costs (estimated at US\$9000) and generate further savings of US\$2000 per year. In this example, the costs of mercury and mercury-free aneroid sphygmomanometers, including taking into account differences in maintenance and calibration costs, were found to be essentially equal, with both devices often being manufactured by the same company.

Key considerations related to development of a national phase-out strategy

- Facility-based demonstrations can be an effective means of raising awareness about the feasibility of implementing phase-out activities. They can provide a useful opportunity to highlight positive examples and demonstrate replicable results. The experience of facilities that have successfully switched to mercury-free devices can serve as models that could be replicated elsewhere.
- A key issue that needs to be considered at an early stage is whether to replace mercury-containing thermometers and sphygmomanometers upon the end-of-service-life or whether to substitute devices progressively location-by-location. The Convention does not require the removal of use of devices already manufactured or imported. Since breakage often defines the end-of-life for these devices, replacement at that time entails considerable risk of mercury releases. Replacement before the end-of-life is generally preferred but other factors may have to be taken into account. Considerations include availability and cost of non-mercury devices at a particular time, the health care facility's budget, availability of clean-up and personal protective equipment, staff training, types of packaging and storage facilities available. In addition, availability of both mercury and non-mercury devices side-by-side may not promote change-over to the non-mercury devices among health care staff. At the national level a combination of both approaches may be taken. The approach taken for thermometers and sphygmomanometers may also differ due to the different average service-life of these products.
- A phase-out strategy should include clear goals, timelines, and short-, medium- and, as relevant, longer-term targets. These should be coupled with clear and measurable performance indicators that can be used in monitoring and evaluating progress made in implementation of the strategy. Provisions should be made for regular review and, if needed, modification of elements in the strategy in case unforeseen issues emerge during implementation.
- Intervention measures put forward in the strategy should take into account and reflect coherence with existing national, sub-national and facility policies and capacities such as those related to procurement, waste management and disposal of mercury-containing medical devices. If these policies and capacities do not exist, are inadequate or not well implemented, consideration should be given to establishing or improving them as they are an integral and essential component of the phase-out process. Particular attention should be paid to policies and capacities related to waste management and disposal of mercury.
- With regard to waste management and disposal options, consideration should also be given to the Basel Convention as this may have implications if export of mercury or mercury waste is considered.
- It may be necessary to establish an accreditation scheme if new products are to be introduced to the domestic market, in particular to ensure that maintenance, validation and procurement of replacement parts and other services are provided by licensed (registered) individuals or entities.
- Consideration may also be given to the possibility of combining phase-out efforts focused on health care with those led by other sectors and stakeholders in order to phase out mercury-containing thermometers and sphygmomanometers used in other settings, such as in veterinary settings. Taking an integrated, multi-settings approach could also increase momentum and demand for alternative products, which could subsequently accelerate production and import of alternatives.

IV. Monitoring and reporting

Monitoring and reporting is an equally vital step in the process of developing (and implementing) a phase-out strategy for mercury-containing measuring devices. Not only is it essential for tracking and evaluating the progress made in achieving phase-out targets; it can also provide useful intelligence about unforeseen or unexpected issues that may have arisen during implementation of the strategy, thus necessitating a change in the overall strategy or implementation approach.

Monitoring activities are likely to consider some of the following:

- compliance with delivery of agreed interventions across all levels of the health system. This might include monitoring of facility-based measures taken to ensure that mercury-containing measuring devices are being appropriately segregated and stored in designated locations and under required conditions. It may also include monitoring of waste collection, transport, environmentally sound disposal and export if applicable;
- the volume of digital thermometers imported, as this can be an indicator of uptake of mercury-free alternatives;
- status of implementation of measures and overall progress in reaching phase-out, replacement or substitution targets;
- rates of incidents and injuries associated with the collection, handling, maintenance, storage and environmentally sound disposal of unwanted, end-of-life or broken devices;

- monitoring the availability of mercury thermometers and sphygmomanometers following the implementation of the phase-out strategy and related device replacement and substitution activities as applicable;
- costs associated with the collection, environmentally sound disposal, replacement, maintenance and use of mercury-free alternatives;
- routine testing, calibration and scheduled preventive maintenance of non-mercury devices;
- number or percentage of health care facilities with substitution or replacement activities;
- change in policies and practices of health care facilities and staff, for example as a result of training and awareness activities.

Key considerations related to monitoring and reporting

- In some instances it may be appropriate to couple routine monitoring and reporting with periodic visits or audits.
- Traceability of mercury-containing products and waste is a growing concern. Traceability encompasses actions, measures and procedures put in place to identify and record all hazardous waste management activities from generation to environmentally sound disposal so as to ensure that such waste is not diverted for illegitimate uses or disposed of inappropriately.

References

1. Shimek J M, Emmanuel J, Orris P, Chartier I, editors. Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance. Geneva: World Health Organization; 2011.
2. Initial Guidelines for Enabling Activities for the Minamata Convention on Mercury. Washington D.C.: Global Environment Facility; 2013.
3. Model policies. In: Mercury-Free Health Care [website]. Argentina: Health Care Without Harm; 2015 (<https://noharm-global.org/issues/global/model-policies>, accessed 16 February 2015).
4. European Commission - Environment/ Chemicals. European Commission; 2014. (http://ec.europa.eu/environment/chemicals/mercury/index_en.htm, accessed 9 September 2014).
5. Substituição dos Dispositivos Hospitalares Contendo Mercúrio INTO - Instituto Nacional de Traumatologia e Ortopedia Jamil Haddad, Rio de Janeiro – RJ – Brasil. In: Global Green and Healthy Hospitals. Washington D.C.: Health Care Without Harm; 2013.

Annotated bibliography

Safe management of wastes from healthcare activities: second edition (WHO, 2014)

This guide provides a comprehensive overview of good practice in managing health care wastes, including wastes containing mercury. Issues related to the handling, storage, transport and disposal of waste are covered. Worker health and safety considerations are also addressed.

Available in English at:
http://www.who.int/water_sanitation_health/medicalwaste/wastemanag/en/ (accessed 26 September 2014).

Guidance on maintaining and calibrating non-mercury clinical thermometers and sphygmomanometers (UNDP, 2013)

This guidance provides information on maintaining and calibrating non-mercury devices commonly used in health care facilities and in low- and middle-income settings. General information is also provided about validation protocols for such devices.

Available in English at:
http://noharm.org/lib/downloads/mercury/Guidance_Hg_2013.pdf (accessed 26 September 2014).

Replacement of mercury thermometers and sphygmomanometers in health care: technical guidance. (WHO, 2011)

This document provides guidance on the safe substitution in health care settings of mercury-containing thermometers and sphygmomanometers by mercury-free devices. It identifies available resources that support the equivalent accuracy and comparable clinical utility of the substituted products, while protecting health care workers and the environment. The guidance is designed to support professionals responsible for institutions or ministries desiring to switch to safer, non-polluting technologies in health care.

Available in English and Russian at:
http://www.who.int/water_sanitation_health/publications/2011/mercury_thermometers/en/index.html (accessed 27 September 2014)
and in Spanish at:
http://www.paho.org/hq/index.php?option=com_content&view=article&id=8162&Itemid=39771&lang=es (accessed 26 September 2014).

Technical guidelines for the environmentally sound management of wastes consisting of elemental mercury and wastes containing or contaminated with mercury (UNEP, 2011)

This document provides guidelines on the environmentally sound management of mercury-containing wastes in accordance with the provisions set out in the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. While not specific to mercury waste in health care facilities, the document contains relevant information.

Available in English at: http://www.basel.int/Portals/4/Basel%20Convention/docs/techmatters/mercury/guidelines/UNEP-CHW-10-6-Add_2_rev_1.pdf (accessed 26 September 2014)

Cleanup, storage and transport of mercury waste from healthcare facilities (UNDP, 2010)

The UNDP-GEF-WHO-HCWH Global Healthcare Waste Project has issued a guidance document on the cleanup, temporary or intermediate storage, and transport of mercury waste from healthcare facilities. As health facilities phase out mercury devices, proper methods of storage and transport are needed. The guidance provided is relevant for contexts where no national norms and guidelines on this topic exist.

Available in English at:
http://www.undp.org/content/undp/en/home/librarypage/environment-energy/chemicals_management/cleanup-storage-and-transport-of-mercury-waste-from-healthcare-facilities/ (accessed 26 September 2014).

Good practices for the management of mercury releases from waste (UNEP, 2010)

This document provides information on good practices to reduce mercury releases from waste following a life-cycle management approach. While not solely or specifically focused on mercury containing health care waste, information provided is relevant.

Available in English at:
http://www.unep.org/chemicalsandwaste/Portals/9/Mercury/Documents/INC2/Good_practices_Oct2010.pdf (accessed 26 September 2014).

Mercury sphygmomanometers in healthcare and the feasibility of alternatives (EU, 2009)

This study addresses the issue of whether the replacement of mercury-containing, blood pressure-measuring devices (sphygmomanometers) would endanger proper health care including specific groups of patients and/or compromise long-term translational epidemiological studies for public health. The availability and quality of alternative devices for blood pressure measurements are also considered.

Available in English at: http://ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o_025.pdf (accessed 26 September 2014).

Essential environmental health standards in health care (WHO, 2008)

This document provides guidelines for setting safety condition standards in health care. It also provides recommendations for minimizing the risk of health care-associated diseases for patients, staff and caregivers. Health care waste management considerations, including for mercury-containing waste are addressed.

Available in English and French at: http://www.who.int/water_sanitation_health/hygiene/settings/ehs_hc/en/ (accessed 26 September 2014).

Mercury in health care (WHO, 2005)

This document provides an overview of problems associated with the use of mercury-containing products in health care, including associated environmental health and occupational health issues. It also outlines a strategy for WHO and health care engagement on this issue.

Available in English, Arabic, Spanish and French at:
http://www.who.int/water_sanitation_health/medicalwaste/mercury/en/
(accessed 26 September 2014).

OTHER RESOURCES

Training video on mercury waste in hospitals (2011)

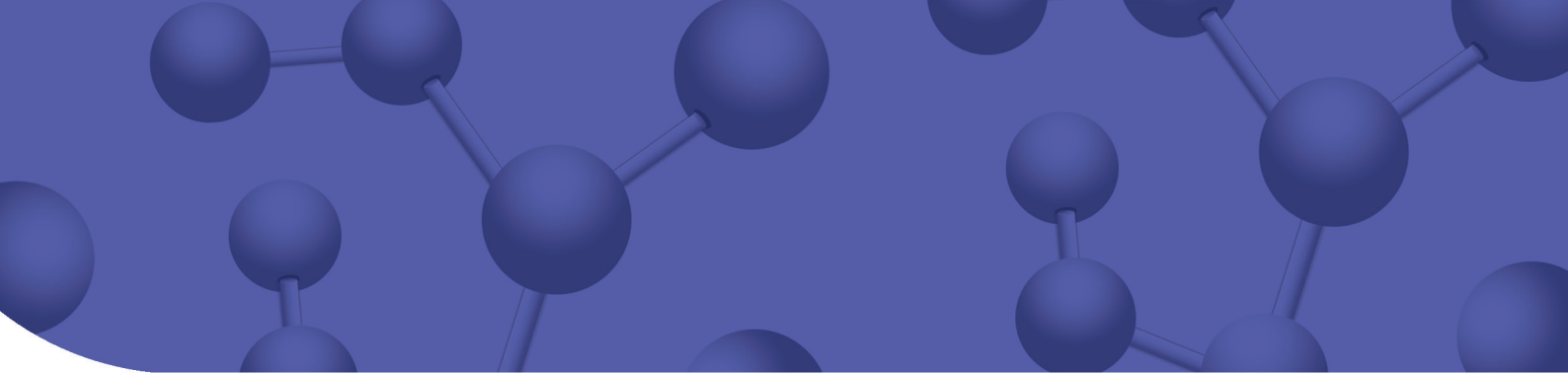
This video can be used as part of a training programme for hospitals which are working to eliminate mercury and safely manage and store mercury waste. The video is based on the UNDP-GEF-WHO-HCWH Global Healthcare Waste Project mercury waste management guidelines.

Available in English and Spanish at:
<https://noharm-global.org/articles/news/global/new-training-video-mercury-waste-hospitals> (accessed 26 September 2014).

WHO training package on children's health and the environment (2008)

A training package for health professionals on children's health and the environment includes a PowerPoint training module on mercury including health hazards associated with mercury exposure, how to diagnose and manage mercury exposure and poisoning and how to prevent and reduce exposure.

Available in English at:
<http://www.who.int/ceh/capacity/Mercury.pdf> (accessed 26 September 2014).



**Department of Public Health, Environmental and Social
Determinants of Health**

World Health Organization

Geneva 27, CH-1211

Switzerland

www.who.int/phe

ISBN 978 92 4 150833 9



9 789241 508339