Mercury in products Area*

Tuesday 13 October 2020
1:30pm – 3pm CEST

Mercury-added medical measuring devices: tools and implementation

Webinar on mercury-added products - #1

UNEP GLOBAL MERCURY PARTNERSHIP

Mercury in products Area*

AGENDA

1:30

Opening remarks and setting the scene

Tom Groeneveld– UNEP Global Mercury Partnership, Products Partnership Area lead

Marianne Bailey - Minamata Convention Secretariat

1:45

Medical Measuring Devices – what is at stake?

Adriana Velazquez Berumen, World Health Organisation

Maggie Montgomery, World Health Organisation

2:15

Sharing national experience and lessons learned: Questions and sharing experiences

All participants

Closure

Tom Groeneveld– UNEP Global Mercury Partnership, Products Partnership Area lead

2:55

Moderated by the UNEP Global Mercury Partnership Secretariat

Overview of the UNEP Global Mercury Partnership and the Products Partnership Area

https://web.unep.org/globalmercurypartnership/

Global Mercury Partnership

- Voluntary multi-stakeholder network initiated in 2005 by UNEP Governing Council
- Overall Goal: to protect human health and the environment from the releases of mercury

Current priority focus:

- Support timely and effective implementation of the Minamata Convention
- Provide knowledge and science on mercury
- Deliver outreach and awareness raising towards global action

Eight Partnership Areas of work

NOVEMBER 2019

UNEP GLOBAL MERCURY PARTNERSHIP

Mercury in products Area*

Partnership Area Lead:
Tanya Hodge Mottley, U.S. Environmental Protection Agency

UN environment programme | GLOBAL MERCURY PARTNERSHIP

ISSUE

Large amounts of mercury are used globally in numerous products and manufacturing processes. Yet, for most products, effective alternatives to mercury are available.

Transition success has been demonstrated in thermometers, switches and relays, batteries other than button cells, thermostats, HID auto discharge lamps, and sphygmomanometers.

Affordable alternatives to mercury are available for most products, but commercially cost-effective alternatives for some products are further needed.

Moving away from mercury-added products is the most effective means to avoid mercury in waste. Sound management should consider all stages of the product's lifecycle. Clear regulation can prompt manufacturers to produce mercury-free products.

OBJECTIVE

The objective of the Partnership Area is to phase out and eventually eliminate mercury in products and to eliminate releases during manufacturing and other industrial processes via environmentally sound production, transportation, storage, and disposal processes.

STRATEGY

The Partnership Area seeks to achieve its goals through:

- Identifying and implementing successful approaches for reducing or eliminating mercury in products where there are effective alternatives;
- Promoting environmentally sound production, transportation, storage, and disposal procedures; and
- Providing a partner-driven forum for exchanging information and discussing strategies for achieving goals and objectives.

CONTRIBUTION TO THE IMPLEMENTATION OF THE MINAMATA CONVENTION

The Partnership Area intends to support countries in implementing their obligations in relation to Article 4 of the Minamata Convention, including through:

- Exchanging and disseminating technical information; and
- Engaging scientific and business communities.

The Partnership Area also contributes to work undertaken by the Conference of the Parties to the Minamata Convention in relation to customs codes.

RELEVANT PROVISIONS OF THE MINAMATA CONVENTION ON MERCURY:

Under **Article 4 (Mercury-Added Products)**, Parties shall not allow the manufacture, import or export of mercury-added products listed in **Part I of Annex A** after the phase-out date specified for those products.

Parties shall also take measures for the mercury-added products listed in **Part II of Annex A**.

Amongst others, Parties shall also discourage the manufacture and distribution in commerce of mercury-added products not covered by any known use prior to the date of entry into force of the Convention for them, unless an assessment of the risks and benefits of the product demonstrates environmental or human health benefits.

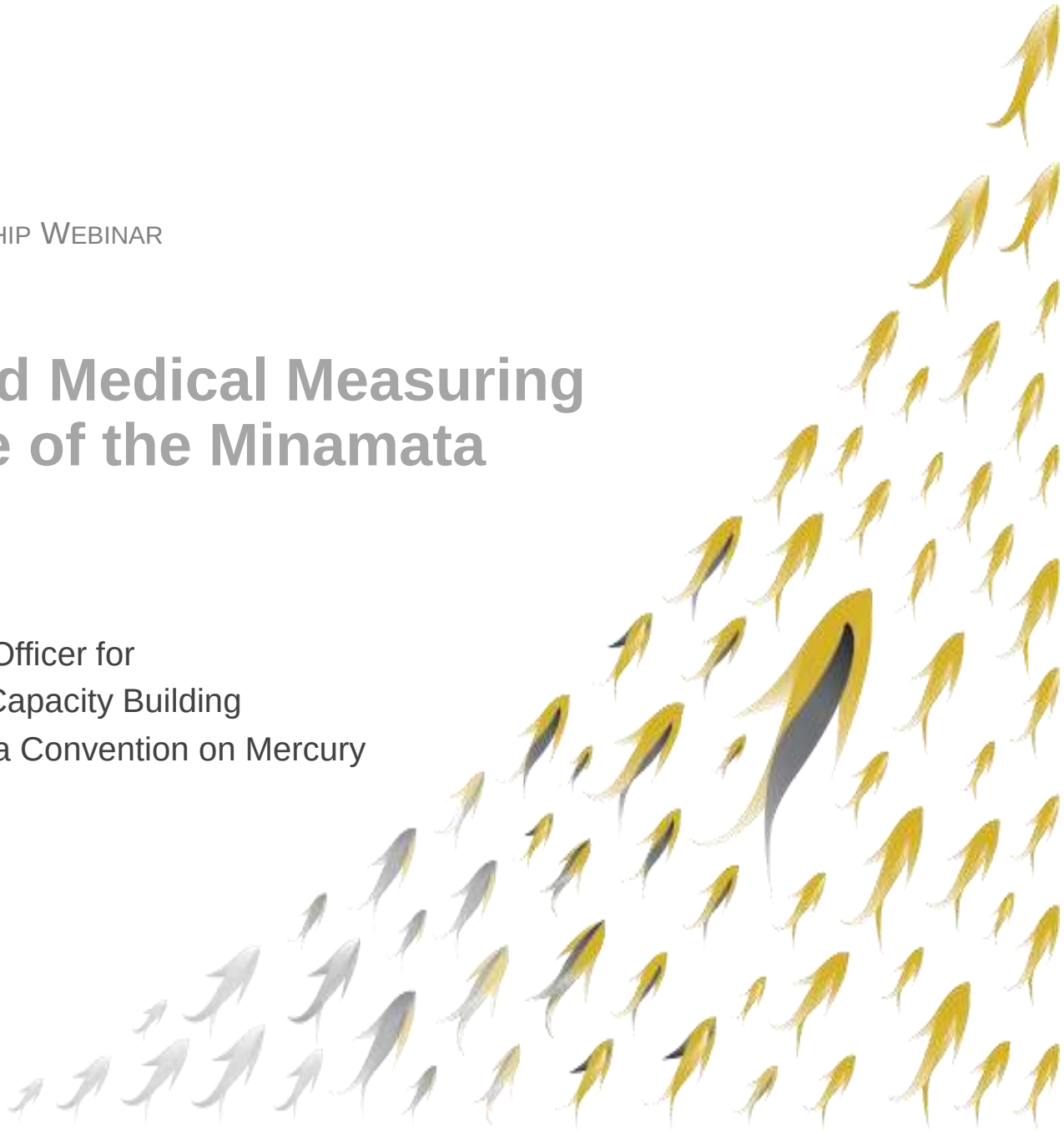
The Secretariat shall collect and maintain information on mercury-added products and their alternatives and make such information publicly available.

* [illegible]

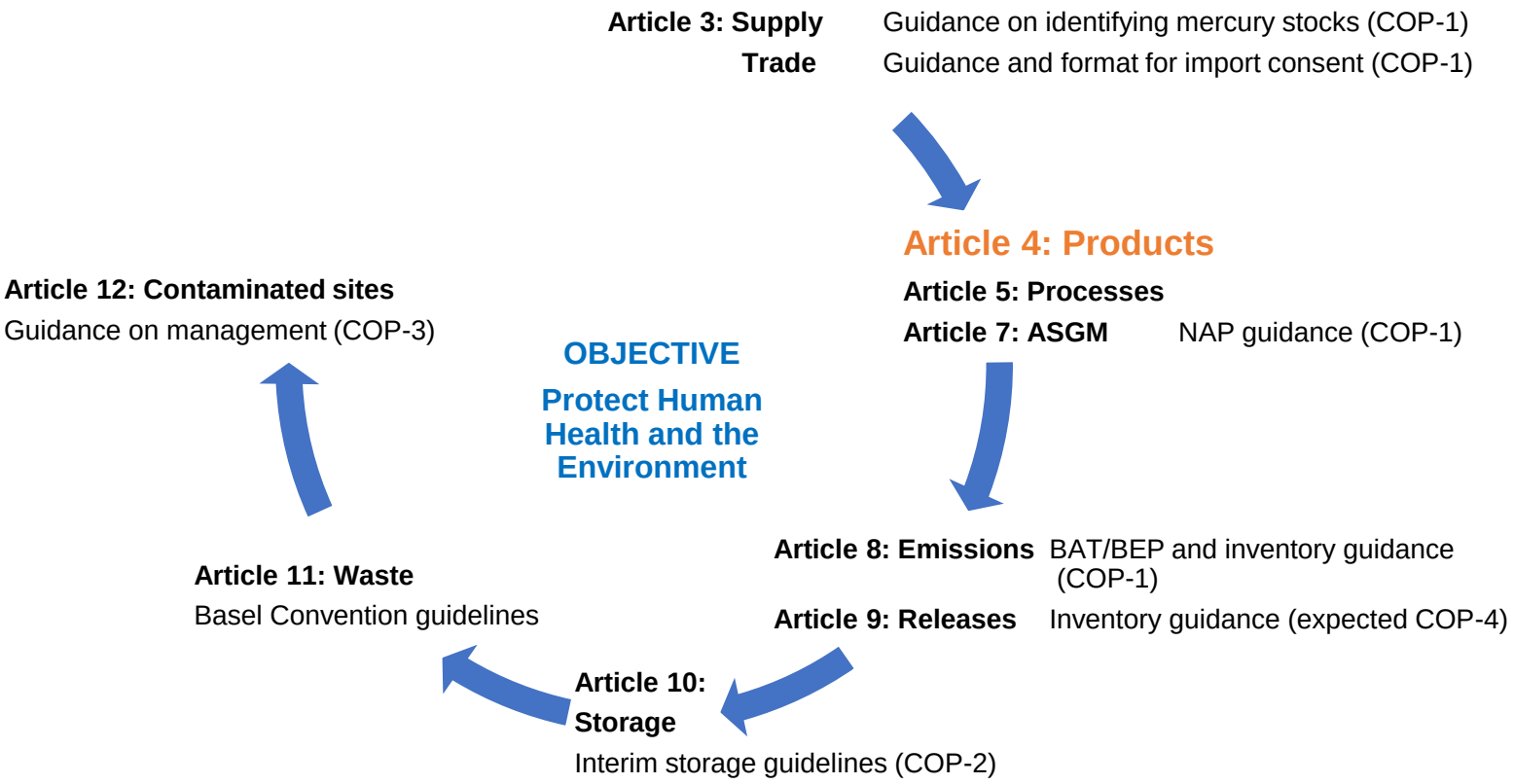
GLOBAL MERCURY PARTNERSHIP WEBINAR
OCTOBER 13, 2020

Mercury-added Medical Measuring Devices: Role of the Minamata Convention

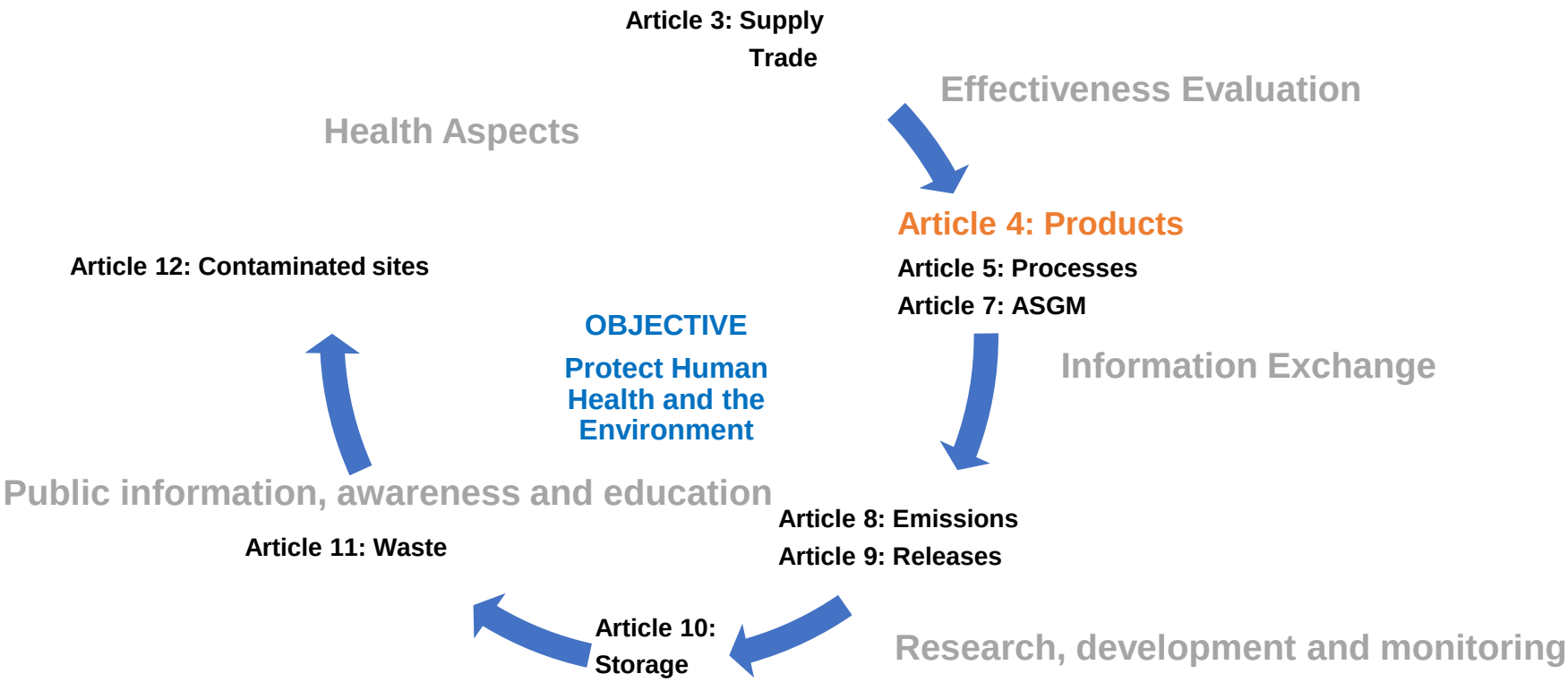
Marianne Bailey
Programme Management Officer for
Technical Assistance and Capacity Building
Secretariat of the Minamata Convention on Mercury



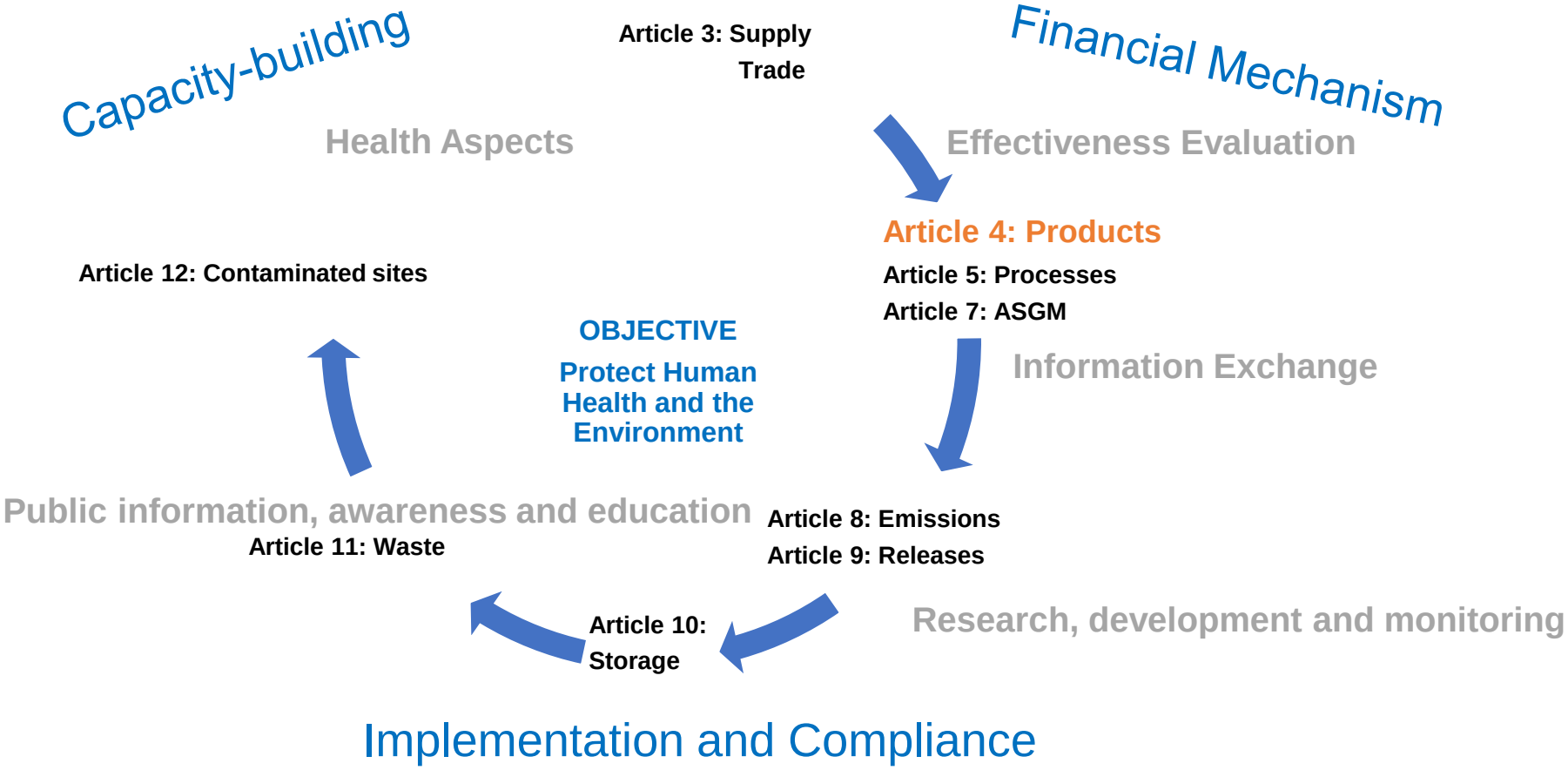
The Minamata Convention



The Minamata Convention



The Minamata Convention



Minamata Convention ARTICLE 4 and ANNEX A

2020

...Shall not allow, by taking appropriate measures, the **manufacture, import or export** of mercury-added products listed in Part I of Annex A after the phase-out date specified for those products…

WHAT IS IN ANNEX A PART I?

Batteries

Switches and Relays

Lamps

- **compact fluorescent (CFLs)**
- **Linear Fluorescent**
- **High Pressure Mercury Vapor**
- **CCFLs and EEFLs**

Cosmetics including skin lightening soaps and creams

Pesticides, biocides, and topical antiseptics

Non-electronic measuring devices

- **barometers**
- **hygrometers**
- **manometers**
- **thermometers**
- **sphygmomanometers**

WHAT IS IN ANNEX A PART II?

Dental amalgam -- measures to phase down

Minamata Convention ARTICLE 4 and ANNEX A:

EXCLUSIONS FROM PHASE-OUT MANDATE

Essential military/police use

R+D/calibration

Replacements

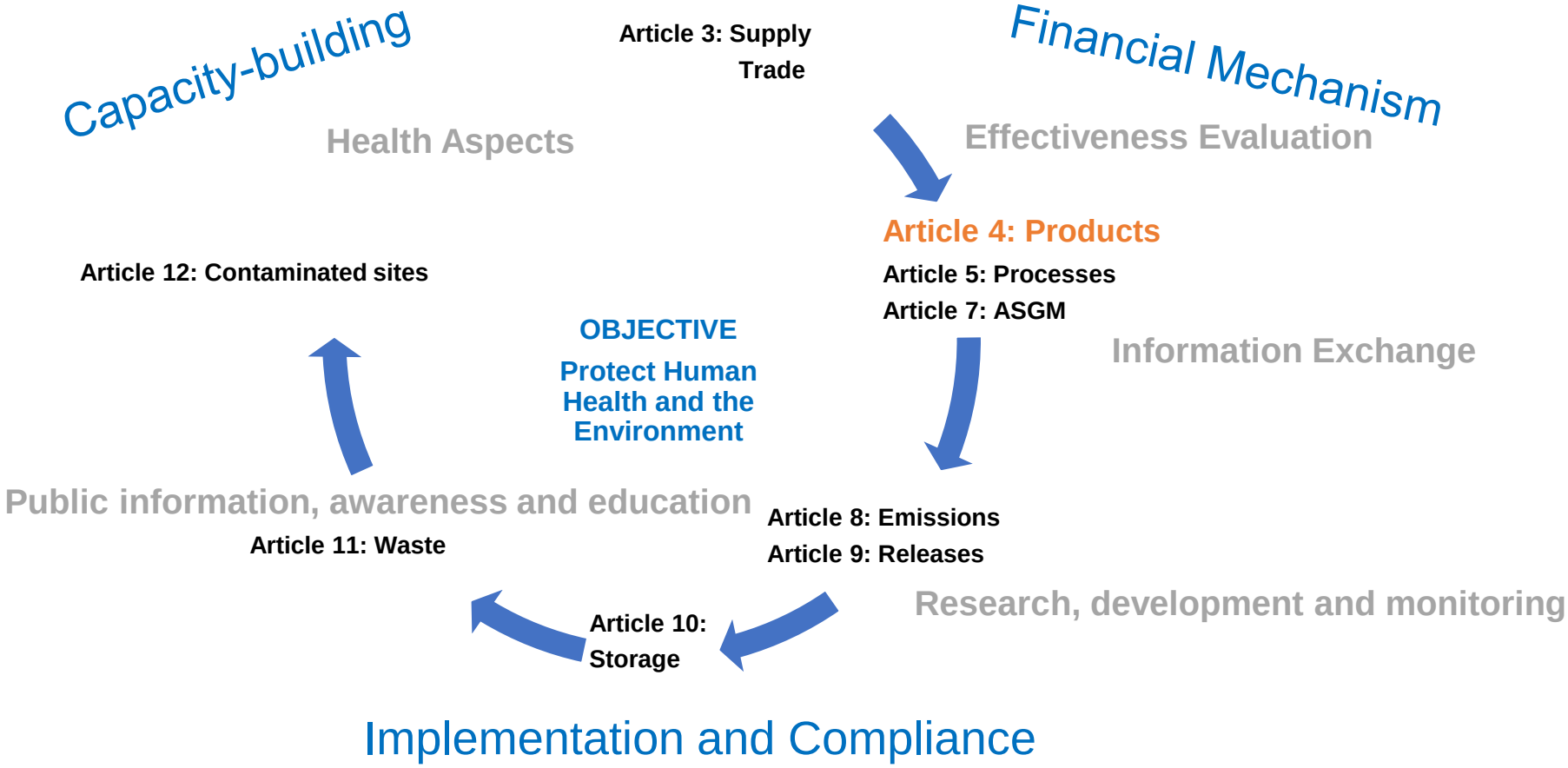
Vaccines

Traditional/religious practices

Minamata Convention ARTICLE 4 and ANNEX A

- No manufacture, import, or export of phased out products after 2020
- Dental amalgam phase down measures
- Prevent mercury components going into larger products
- Discourage mercury-added products previously unknown

The Minamata Convention



More information and how to contact the Convention Secretariat

WEB www.mercuryconvention.org

E-MAIL MEA-MinamataSecretariat@un.org

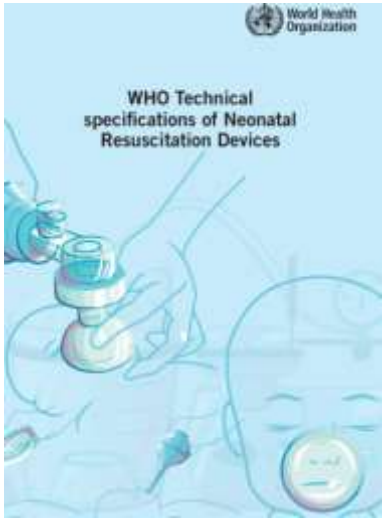
TWITTER @minamataMEA#MakeMercuryHistory

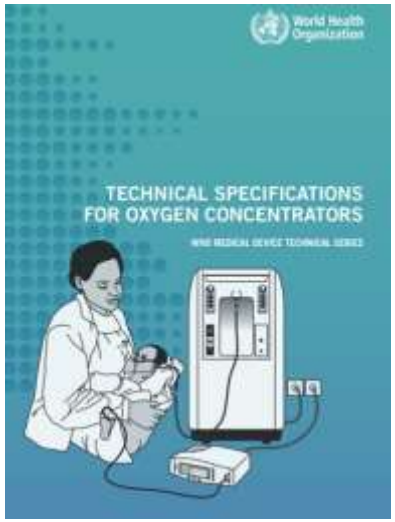
Blood pressure measurement devices, guidelines and technical specifications

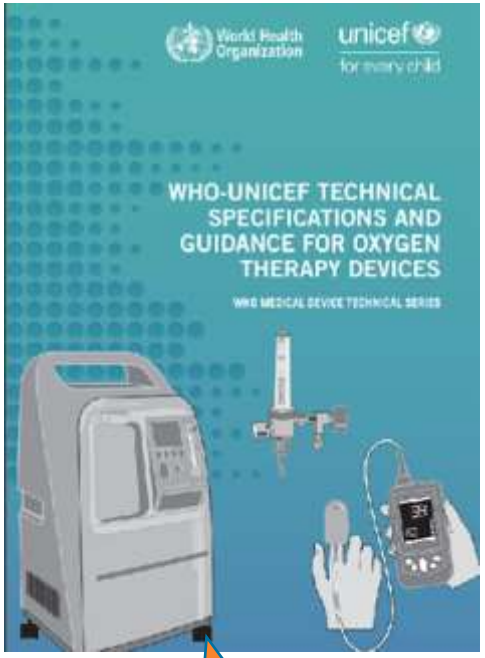
World Health Organization

2. Technical specifications for procurement

World Health Organization

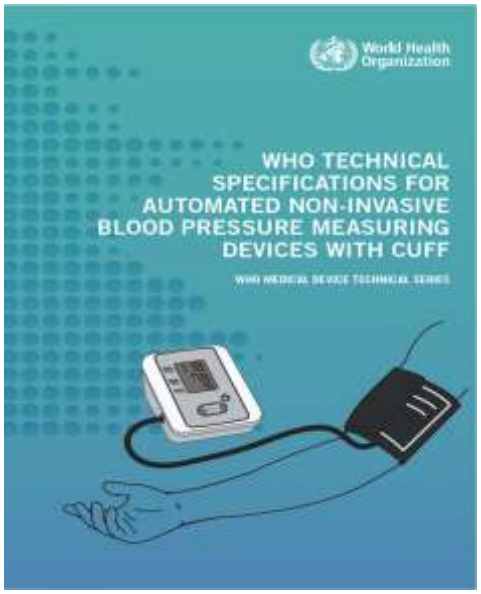






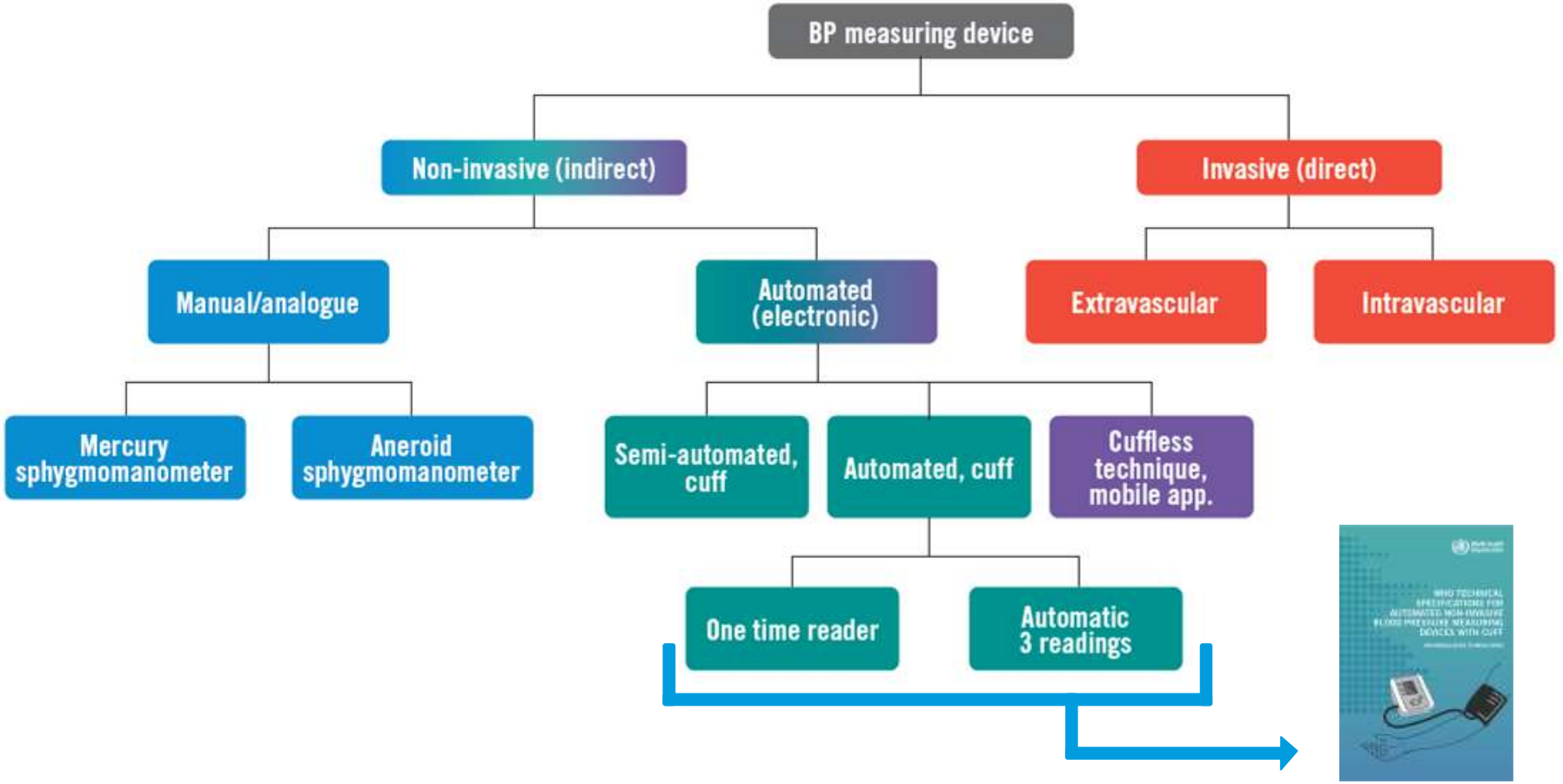
2019

2020



https://www.who.int/medical_devices/publications/tech_specs_automated_non_invasive_blood_pressure_with_cuff/en/

SELECTION & SCOPE



	Manual / analogue		Electronic / automated			
Type	**Mercury sphygmomanometer**	**Aneroid sphygmomanometer**	**Semi-automated, cuff**	**Automated, cuff**		**Cuffless technique, mobile app.**
Illustration						
Recommend?	No longer, because of toxicity of mercury	Not recommended because requires frequent recalibration and observer training and retraining	Only accuracy validated automated BPMDs are recommended for clinical use			Not suitable or recommended for clinical use because of lack of universal standards for validating the accuracy of BP measurements
Reference on publication	Annex 6. Technical specifications and use of manual non-invasive BPMDs		Chapter 3. Automated non-invasive BPMDs			Chapter 5. Innovation and research
Brief description	Pressure cuff, hand pump, mercury column, stethoscope	Pressure cuff, hand pump, aneroid (mechanical transducer), stethoscope	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
Method of BP estimation	Detection of Korotkoff sounds through a stethoscope for auscultation.		Two possible methods: 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

Subcategories of non-invasive Blood Pressure Measuring Devices

1

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.

2

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

3

World Health Organization

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

5

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

Annex 3

Universal standard for the validation of blood pressure measuring devices

World Health Organization

A Universal Standard for Validation of Blood Pressure Measuring Devices was developed by: The Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) in 2018.

It is named: ISO 81060-2:2018(en), Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type

History of validation protocols

Publication	Organization
1987, 1992, 2002	US Association for the Advancement of Medical Instrumentation (AAMI)3, 5
1990, 1993	British Hypertension Society (BHS)4, 6
1999	German Hypertension League (Deutsche Hochdruckliga) (DHL)7
2002, 2010	European Society of Hypertension International Protocol (ESH-IP)8, 9
2004	European Committee for Standardization (CEN)10
2009	International Organization for Standardization (ISO)11
2009, 2013	American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO)12, 13
2018	Association for the Advancement of Medical Instrumentation/European Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO)14.

1

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

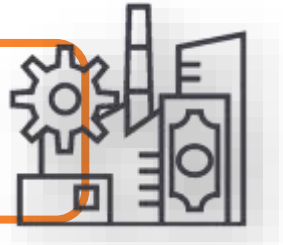
	Manual / analogue	
Type	**Mercury sphygmomanometer**	**Aneroid sphygmomanometer**
Illustration		
Recommend?	No longer, because of toxicity of mercury	Not recommended because requires frequent recalibration and observer training and retraining
Reference on publication	Annex 6. Technical specifications and use of manual non-invasive BPMDs	
Brief description	Pressure cuff, hand pump, mercury column, stethoscope	Pressure cuff, hand pump, aneroid (mechanical transducer), stethoscope
Method of BP estimation	Detection of Korotkoff sounds through a stethoscope for auscultation.	

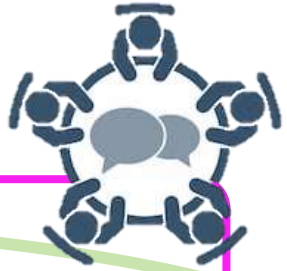
To ensure improved access of safe, quality medical devices

World Health Organization

R&D

- Industry and Academics: Research and development <u>should be based on needs</u>





Assessment

- Health Technology Assessment
- Lists of MD for reimbursement or public procurement

Common elements in dossier

Regulations

- Regulation process of medical devices
- Lists of approved devices for marketing in country.

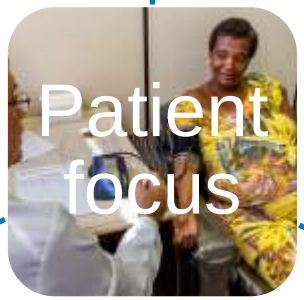
Management

- Needs Assessment and Selection
- Incorporation: (technical specifications for procurement, donations)
- Safe use,
- Post market surveillance and adverse event report
- Decommissioning,

Next steps . The use of the WHO guidance to ensure best patient outcomes

World Health Organization

Health ministers for policies



Regulatory and Procurement agencies to ensure good quality products are used

For manufacturers to produce quality products

Remember a patient is at the end of all our activities, they deserve our:

- Technical knowledge
- Passion
- Honesty
- Hard work
- Together

Innovative technology should be:

Safe
Good quality!
Easy to use
Easy to maintain
Adaptable
Affordable
Available
Accessible
Acceptable

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

World Health Organization
20, Avenue Appia 1211 Geneva, Switzerland

Adriana Velazquez Berumen
velazquezberumena@who.int

www.who.int/medical_devices

World Health Organization

Policy guidance and lessons learned from phasing-out of mercury thermometers and sphygmomanometers in health care

Maggie Montgomery
Water, Sanitation, Hygiene and Health Team
World Health Organization
Geneva

The challenge: WASH in health care facilities, globally

Find your country's data:
www.washdata.org/healthcare

- 1 in 4 lack basic water
- 1 in 10 have no sanitation
- 1 in 3 lack hand hygiene at point of care
- 1 in 3 lack systems to segregate waste
- Services drop by 50% in least developed countries

New data for 164 countries now online!
(from 473 data sources)

For detailed analysis of 2019 baseline data see: WHO/UNICEF, 2019 Global Baseline Report
https://www.who.int/water_sanitation_health/publications/wash-in-health-care-facilities-global-report/en/

Leveraging commitments and a movement on WASH and waste

WASH in Health Care Facilities

Calls for Countries to:

- Establish **national roadmap, targets** and implement WASH in HCF and infection prevention and control (IPC) standards
- Integrate WASH and IPC **standards and indicators** into health programming and monitoring
- **Address inequities**, especially in primary health care facilities and facilities where births occur
- Increase **domestic funding** for WASH in HCF

2019 World Health Assembly Resolution on WASH in health care facilities

Calls for the WHO Director General:

- Provide leadership, technical guidance and regularly report on status
- Mobilize partners and investments

Full text of resolution
http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R7-en.pdf

Mercury release from healthcare facilities

The incineration of mercury-containing medical waste is a source of mercury releases into the atmosphere.

Healthcare facilities may also be responsible for mercury pollution taking place in water bodies from the release of untreated wastewater.

Breakage of mercury thermometers and sphygmomanometers, if not dealt with appropriately, can result in occupational (and patient) exposures

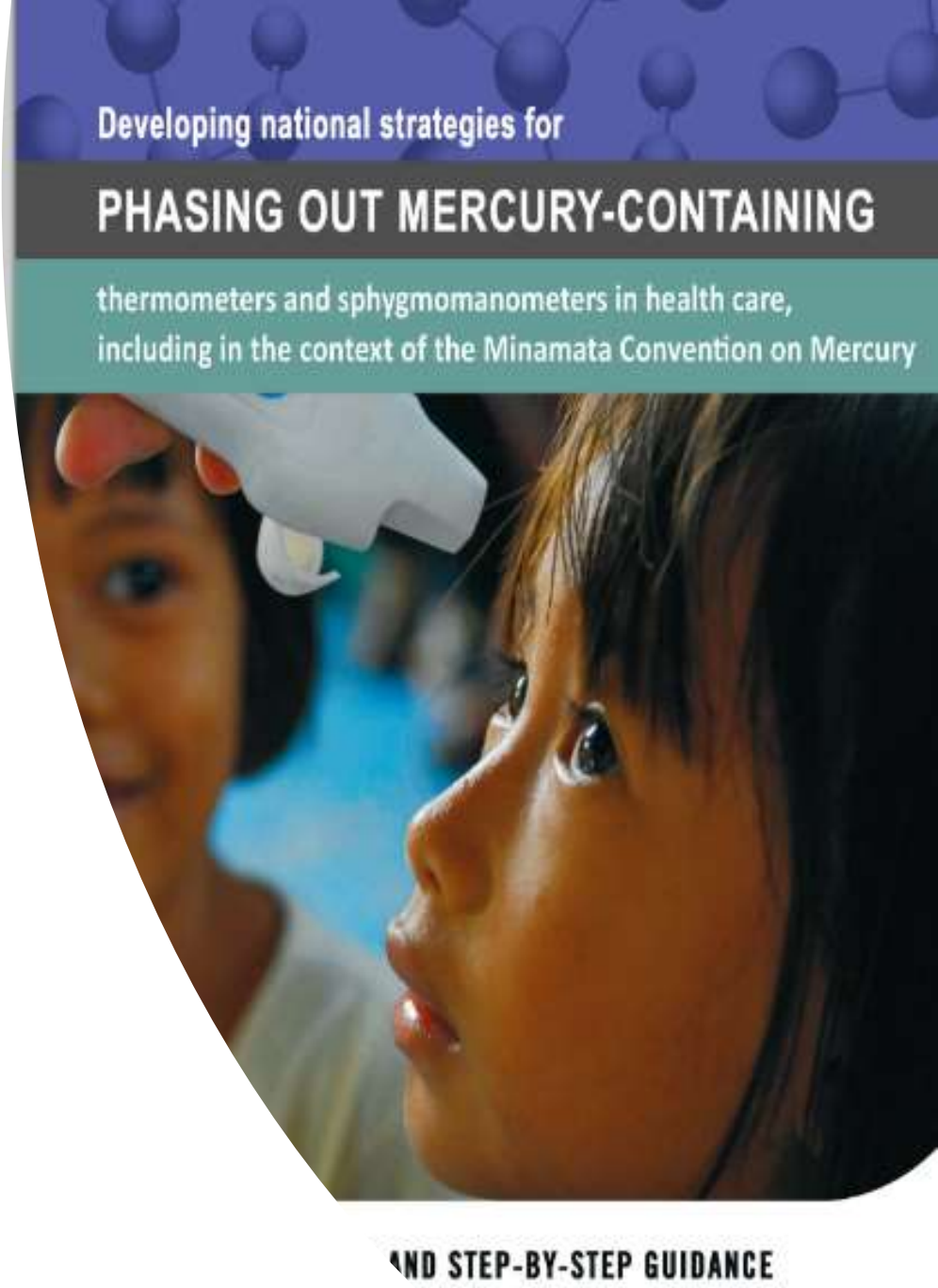
WHO guidance: developing a national strategies to phase out mercury thermometers and sphygmomanometers

Scope and purpose:

Address phasing out of mercury containing thermometers and sphygmomanometers in health care

Facilitate development of health-system-wide approaches, building on successes and good experiences at the level of individual institutions

Provide suggested process, highlighting specific issues that may warrant greater consideration depending on the national context



Step 1: Develop a stakeholder engagement strategy

set management and oversight arrangements for development and implementation of the strategy and interventions

identification of stakeholder groups needed to support roll-out

establishment of process for engaging stakeholders (several of whom may not be the same) in strategy development and implementation

Step 2: Situation assessment and inventory

number/quantity of medical devices requiring **replacement** or **substitution**

volume of waste material to be collected, stored and disposed

capacity to support phase-out activities and identification of gaps, including

- availability of mercury-free devices and products
- availability of supporting services e.g. maintenance, validation, calibration
- capacity for safe collection, storage, and environmentally sound disposal

Step 2: Situation assessment and inventory (continued)

identification priority areas (e.g. locations, facilities) to be targeted for initial activities

costs associated with potential phase-out scenarios

recommendations on available options for implementation of phase-out activities

Step 3: Strategy development and implementation

Definition of specific interventions, for example to address/ensure:

- Training and sensitization activities to support the switch to alternative (mercury-free) devices
- Testing of new products to ensure relevant regulatory requirements in place
- Development/updating of technical specifications for essential health commodities lists used for procurement
- Development of operating procedures on safe collection, transport, treatment and environmentally sound disposal of waste

Step 3: Strategy development and implementation (continued)

Agreement reached on roles and responsibilities for delivery of phase-out activities

Establishment of monitoring framework for reporting on delivery of interventions and any unforeseen or unexpected issues/impacts

Step 4: Monitoring and reporting

Monitoring of results of interventions and supporting activities

Adjustment of strategic approach as needed, taking into consideration lessons learned

Detection and reporting, of unforeseen issues/impacts related to the implementation of measures under the strategy

Insights from strengthening safe health care waste management, including phasing out mercury in Ghana, Madagascar, Tanzania and Zambia

Lesson 1. Understand existing quality standards and processes and work to strengthen them

Challenges

- Weak quality control system for medical devices in the countries
- Low capacity for validation, calibration of medical equipment

Solutions

- Establish quality control system
- Train procurement staff onsite on how to check quality of equipment
- Assess country capacity on validation and calibration
- Provide clear guidance and training on validation and calibration

Lesson 2. Understand who owns thermometers and what needs replacing

Challenges

- Medical devices often owned by patients and doctors; not the health care facility.
- Equipment often lacking and shared and a 1:1 replacement may be insufficient or raise contamination concerns.

Solutions

- For an exchange, final recipients must be clearly identified and if necessary changed.
- Provide mercury free devices in accordance with need; consider higher budget for new devices to enable staff to use safely.

Lesson 3. Train on use of new devices and put in systems to ensure operation and maintenance

Challenges

- Medical staff not convinced new equipment is as accurate as mercury equipment
- Concerns about replacing batteries-including supply chains
- One size arm-cuffs not suitable for children

Solutions

- Final recipients must be clearly identified and if necessary changed; provide mercury free devices in accordance with need; consider higher budget for new devices
- Establish a maintenance system and reliable energy supply (batteries)
- Consider needs of all users (e.g. children)

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