



Decommissioning Medical Devices

WHO Medical Device Technical Series





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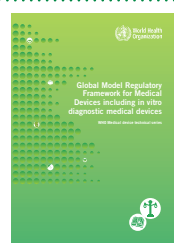
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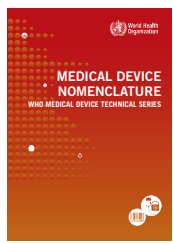
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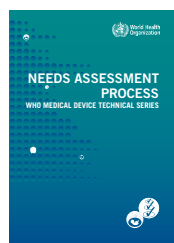
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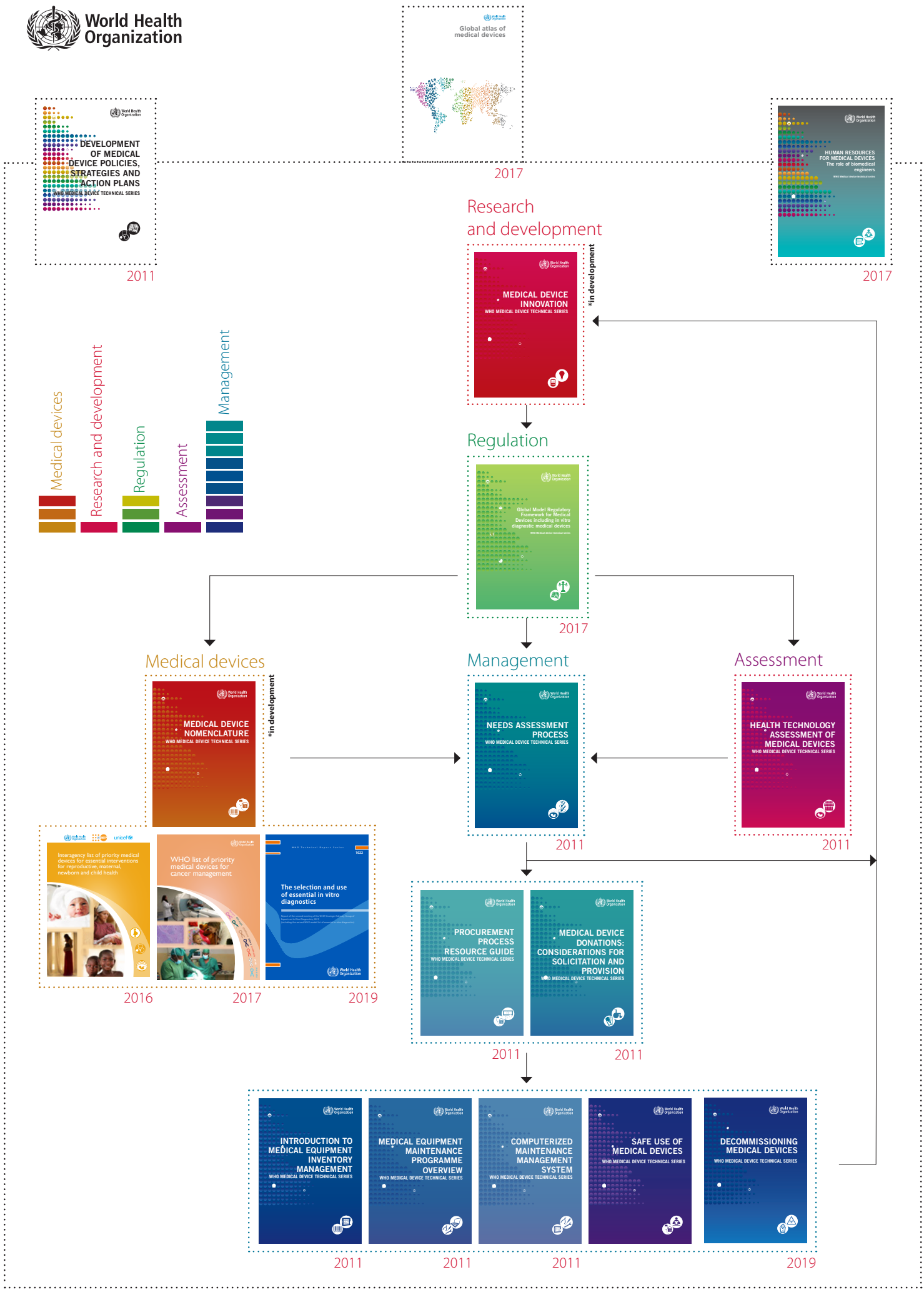
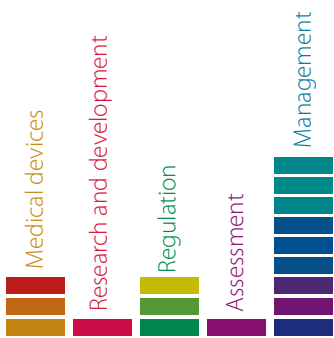


2011

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2019



Decommissioning of Medical Devices

WHO Medical Device Technical Series



Decommissioning medical devices

(WHO medical device technical series)

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Glossary

As the terms listed below have multiple interpretations, they are defined here as used in this technical series and other WHO publications (1,2).

Cannibalization: Practice of recycling properly functioning parts or modules of a medical device for repair of a similar device; a form of reassignment.

Chemical safety: Measures taken to protect the user, patient and environment from any harmful effects of exposure to chemicals.

Chemical waste: Waste consisting of solid, liquid and/or gaseous chemicals that may be toxic, corrosive, inflammable, reactive and/or oxidizing.

Cleaning: A first step required to physically remove contamination by foreign material such as dust or soil; also, to remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a medical device for disinfection or sterilization.

Controlled landfilling: Operating practices and design improvements to reduce the health and environmental impacts of waste disposal in landfills.

Decontamination: Removal of soil and pathogenic microorganisms from objects to make them safe to handle, subject to further processing, use or discard (3).

Decommissioning: Removal of medical devices from their originally intended uses in a health care facility to an alternative use or disposal.

Disinfection: Reduction of the number of microorganisms (but not usually of bacterial spores), without necessarily killing or removing all organisms, usually from non-living objects such as laboratory equipment and laboratory benches.

Disinvestment: Withdrawal of medical devices from the health care system on the basis of evidence that they are clinically ineffective, unsafe, inappropriate or not cost-effective.

Disposal: Intentional burial, deposit, discharge, dumping, placing or release of any waste material into or on air, land or water without the intention of retrieval. In the context of radioactive waste management, disposal is the placement of waste in an approved, specified facility (e.g. near-surface or geological repository) or approved direct discharge into the environment.

Donation: Giving an item or service free of charge.

Electrical safety: Measures taken to protect users, patients and the environment from the harmful effects of electrical malfunction.

Electronic waste: Electrical or electronic equipment that is waste, including all components, sub-assemblies and consumables that are part of the equipment at the time the equipment becomes waste (Basel Convention Technical Guidelines).

Hazardous waste: Waste that is potentially harmful to human beings, property or the environment, such as used reagent strips contaminated with human blood, reagent solution containing sodium oxide and decommissioned instruments containing heavy metals, including waste that is inflammable, combustible, ignitable, corrosive, toxic, reactive, injurious or infectious.

Intended use or purpose: The objective of the manufacturer with regard to use of a medical device, process or service as reflected in the specifications, instructions for use and information provided by the manufacturer.

In vitro diagnostic medical device: A medical device, to be used alone or in combination, intended by the manufacturer for in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. Include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles. Used, for example, for diagnosis, aid to diagnosis, screening, monitoring, identification of predisposition, prognosis, prediction or determination of physiological status.

Labelling: Information about identification, technical description, intended purpose and proper use of a medical device; excludes shipping documents.

Manufacturer: The person or party responsible for designing, manufacturing, packaging and labelling a device before placing it on the market; also responsible for providing documentation, instructions and recommendations for the installation, use and maintenance of the device to ensure its performance, as well as the safety of patients and health workers.

Medical device: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific purposes of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by in-vitro examination of specimens derived from the human body.

A medical device does not achieve its primary intended action by pharmacological, immunological or metabolic means (1).

Medical device life cycle: All phases of the life of a device, from conception to final decommissioning and disposal.

Non-hazardous waste: Waste that does not pose a biological, chemical, radioactive or physical hazard.

Radiation safety: Measures to protect users, patients and the environment from the harmful effects of radiation.

Radioactive waste: Waste containing radioactive substances.

Reassignment: Transfer of a medical device internally or externally to another unit or facility.

Recycling: Converting waste into a reusable material or returning materials to an earlier stage in a cyclic process. Note that recycling is distinct from reuse.

Refurbishing: Reconditioning medical devices for safety and effectiveness with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and their original intended use.

Reprocessing: Steps performed to decontaminate a reusable or single-use device for use in patients, including cleaning, functional testing, repackaging, relabelling, disinfection or sterilization.

Reprocessor: Person or party responsible for completing and ensuring that the requirements for reprocessing a medical device are fulfilled.

Reusable medical device: A medical device that is intended for repeated or multiple uses, for which instructions for reprocessing (decontamination, cleaning, disinfection or sterilization) between uses as well as the limits for reprocessing and reuse are provided.

Sharps: Items that can cause cuts or puncture wounds and pose potential risks of injury and/or infection.

Single-use medical device: Also referred to as a “disposable device”, intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned, disinfected or sterilized) or used on another patient. Labelling should identify the device as single use or disposable and does not include instructions for reprocessing.

Sterilization: A validated process to render an object free from viable microorganisms, including viruses and bacterial spores.

Trade-in: Return of a medical device (sometimes partial) as payment for a replacement.

Uncontrolled dumping: Practice of deposition of wastes at an uncontrolled site, which can lead to pollution, fires, risks of disease transmission and access by human and animal scavengers.

Upgrade: Improvement of a medical device by adding or replacing components and/or updating software.

Preface

Medical devices are essential components of the health care system and are crucial in the prevention, diagnosis and treatment of disease and in rehabilitation. In recognition of the importance of health technology, the World Health Assembly adopted resolution WHA60.29 in May 2007 (4), which addresses issues arising from inappropriate deployment and use of health technologies, specifically medical devices, and the importance of establishing priorities in their selection and management. By adopting this resolution, Member States acknowledged the importance of health technologies for achieving health-related development goals, urged expansion of expertise in the field and requested that WHO specifically support Member States in achieving WHO's strategic objective to "ensure improved access, quality and use of medical products and technologies".

To meet this objective, WHO is devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series for use at country level that cover the following subject area, on which guidance has been published:

- Development of medical devices policies, 2011 (5)
- WHO model regulatory framework for medical devices including in vitro diagnostics (IVD) devices, 2017 (6)
- Health technology assessment of medical devices, 2011 (7)
- Health technology management
 - › Needs assessment for medical devices, 2011
 - › Procurement process resource guide, 2011
 - › Medical device donations: consideration for solicitation and provision, 2011
 - › Medical equipment inventory management, 2011
 - › Medical equipment maintenance programme overview, 2011
 - › Computerized maintenance management systems, 2011
- Priority and essential medical devices
 - › Interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health, 2015 (8)
 - › WHO list of priority medical devices for cancer management, 2017 (9)
 - › First WHO list of essential in vitro diagnostics, 2018 (10)
 - › Second WHO list of essential in vitro diagnostics, 2019 (11)
- Medical device innovation, research and development
 - › WHO compendium of innovative technologies for low-resource settings, 2011, 2013, 2014, 2015, 2018 (12)

These documents are intended for use by policy-makers, biomedical engineers working in health care settings and government institutions, hospital and clinical managers, donors of medical devices, nongovernmental organizations that work in health technology, academic institutions studying health technology and district, national, regional and global managers.

This document is based on WHO guidance in 2011, when it was acknowledged that decommissioning of medical devices appropriately is as important as commissioning and procuring them. Because of the large number of health technologies currently available, decisions to decommission and disinvest are gaining in importance in the selection of health technologies in countries.

The topic of decommissioning medical devices has been addressed by the WHO medical devices unit in global forums. Drafts of this publication were reviewed by experts convened in 2016 and 2018 to ensure their coherence with recent WHO guidance and international publications. All experts involved in preparing these documents completed declarations of interest, and no conflicts were identified. Humatem, Health Technology Assessment International and the International Federation for Medical and Biological Engineering are nongovernmental organizations in official relations with WHO. Their approved work plan included providing technical expertise on a range of topics, including decommissioning, disinvestment and donation.



1. Introduction and purpose

Health technology is an indispensable component of effective health care. Of these technologies, medical devices provide the foundation for prevention, diagnosis and treatment of illness and disease and rehabilitation. There are over 20 000 types of medical device (13), ranging from basic tongue depressors to stethoscopes, surgical instruments, prostheses, in vitro diagnostics (IVDs) and complex medical imaging equipment.

In 2017, the global medical device market was estimated to be worth US\$ 389 billion (14), and it is expected to be worth over US\$ 600 billion by 2024 (15). It has grown significantly over the past two decades, reaching the highest levels in the most advanced hospital systems in high-income countries. Many essential medical devices, however, still fail to reach hospitals and health care centres in low- and middle-income countries, although the availability, accessibility and effective use of essential medical devices play a critical role in achieving health system performance goals and in the cost and quality of medical care that a population receives.

Decommissioning is removal of medical devices from their originally intended use in a health care facility to an alternative use or disposal. WHO has issued a series of technical publications on the assessment, selection and management of medical technology, but, until now, there has been no guidance on decommissioning medical devices and no systematic review

of the economic, environmental and health implications of decommissioning. Reducing disparities in access to medical devices is a complex challenge, as it requires assessment of regulatory, technology, management and procurement systems.

This guide was created in response to insufficient knowledge about decommissioning medical device and is part of the WHO Medical device technical series. The purpose of the document is to guide the process of decommissioning and provide tools for determining why, when and how to decommission medical devices. It is intended to be flexible and adaptable to various environments and health systems, especially in low- and middle income countries. The document is for those involved in health technology policies and implementation: policy-makers, biomedical and clinical engineers in government and facility regulatory agencies, health technology managers, health care facility managers, health care workers who use and handle medical devices, waste handlers and other users of health care technology. Proper decommissioning of medical devices can ensure patient safety and improve the quality of health care, in accordance with Sustainable Development Goal 3: Health and well-being. The publication also includes disinvestment, a policy decision to withdraw health technology from a health care service when there is evidence that it is clinically ineffective, unsafe, inappropriate or not cost-effective.

2. Medical devices

According to the definition of the Global Harmonization Task Force (16), medical devices are any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related articles intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;

- disinfection of medical devices; or
- providing information by means of in-vitro examination of specimens derived from the human body.

Medical devices do not achieve its primary intended action by pharmacological, immunological or metabolic means.

2.1 Life cycle

The life cycle of medical devices encompasses all phases, from their conception to final decommissioning and disposal (Fig. 1). This cycle is most relevant for reusable medical devices but is also applicable to those for single use. As computer software used in medicine is also classified as a “medical device”, the

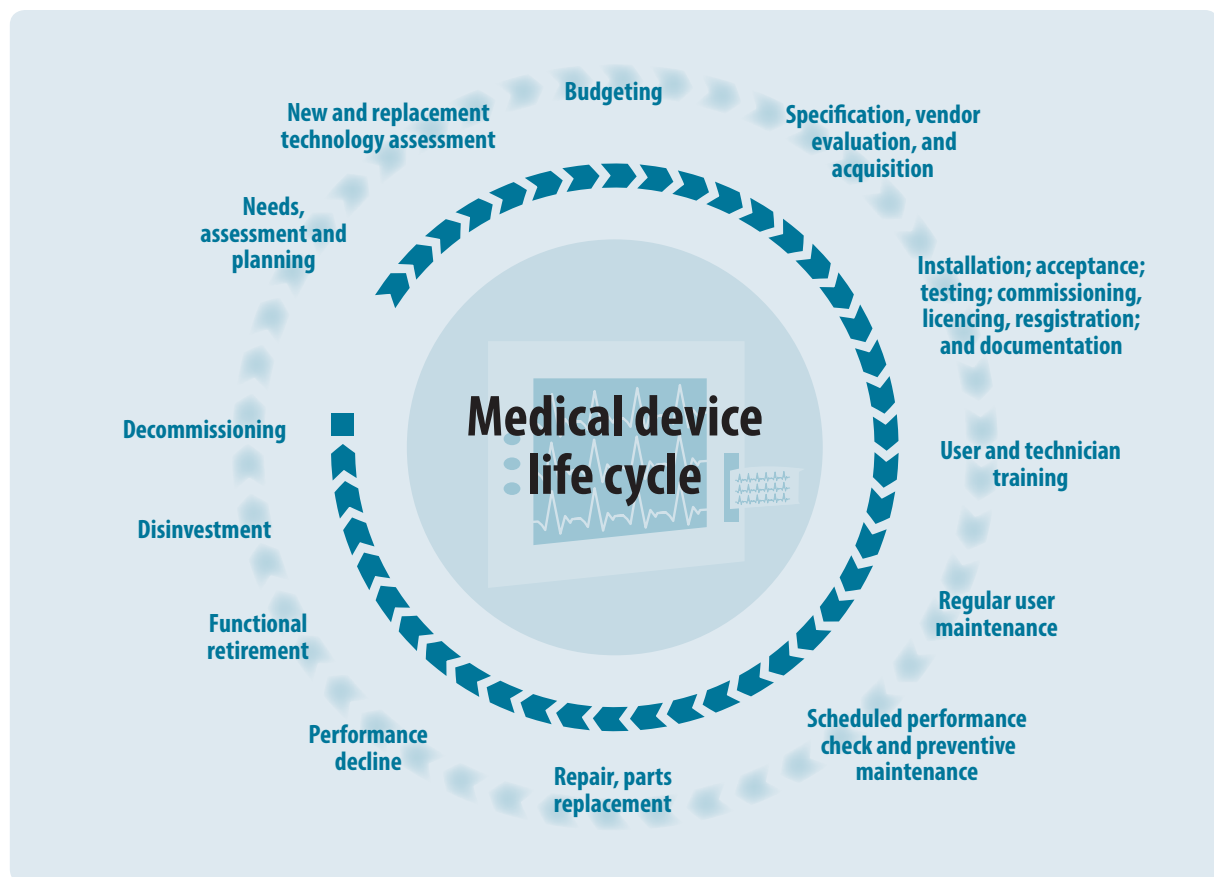


Fig. 1. Medical device life cycle

concepts of “life cycle” and “decommissioning” also apply to software. For more information on decommissioning of computer software, see section 7.7.

The life cycle begins with the requirement for a medical device. The next step is planning its procurement, which includes cost assessment and selection of the most appropriate device and its consumables and accessories to meet the need or purpose. A health care facility may have to prepare infrastructure for the device, with guidance from the manufacturer. Installation, commissioning, acceptance testing and calibrating are performed after acquisition to ensure that the device meets the manufacturer’s specifications and safety standards. Complete information on the device should then be registered in an inventory. Training in the use, maintenance, calibration, repair and checking of the device should be provided to the intended user, biomedical or clinical engineers and any personnel responsible for managing and maintaining the device in the health care facility. Regular preventive maintenance should be performed to prolong the longevity, performance, integrity and safety of the device. Complete guidelines on the various phases are available in the WHO Medical devices technical series (17), and, to provide guidance on effective medical equipment management, WHO has published Medical Equipment Maintenance Programme (18). Reference to this document is recommended for more information on inspection and preventive, corrective maintenance.

After extended use, medical devices deteriorate and reach a state in which the cost–benefit ratio is negative, with declining performance, unreliability and regular failure. Their replacement should follow a clear policy, with evidence-based procedures, and the replacement plan should be based on the history of existing devices, including their safety, reliability and cost. When a medical device becomes obsolete or unusable or is no longer required by the health care facility, it enters the final stage of its life cycle: decommissioning.

2.2 Further reading

Australian regulatory guidelines for medical devices. 1.1 edition. Woden: Australian Government Department of Health and Ageing, Therapeutic Goods and Administration; 2011.

Managing medical devices. London: Medicines and Healthcare Products Regulatory Agency; 2015.

Medical Device Act (Act 737), Medical Device Authority, Ministry of Health Malaysia; 2019. <https://portal.mda.gov.my/documents/surat-pekeling-pbpb-mda-s-circular-letter/mda-s-circular-letter/1112-surat-pekeling-bil-2-2018-rev-1/file.html>.

Medical devices: Managing the mismatch. Geneva: World Health Organization; 2010.

3. Decommissioning

Health care decision-makers are obliged to use their resources rationally and efficiently and to base their actions on well-determined factors in order to avoid unnecessary investments that might be a significant economic burden on their organizations. Decommissioning is removal of a medical device from service in a health care facility after a decision to disinvest (see section 4) in the device itself or in a service in which it is used. The two main pathways for decommissioning a medical device and determining its final disposition after decontamination are permanent elimination (e.g. recycling, cannibalizing or incineration) and re-use (i.e. donated, sold, refurbished, reprocessed, traded-in or reassigned internally to another location) (Fig. 2).

The factors that determine which of the two pathways of the decommissioning is followed can be categorized as those intrinsic to the device, to the infrastructure in which it operates, is being

used or the spaces of transit, and the factors related to administrative or policy decisions.

Factors intrinsic to the device include:

- single-use designation,
- inadequate disinfection or sterilization,
- unresolved performance issues,
- unresolved safety issues,
- continuous unreliability or history of serious failure,
- high cost of repair making the device cost-effective or financially unviable, and
- end of life.

Factors related to the infrastructure (decision to be made by local health care workers) are:

- reorganization, closure or relocation of the health care facility;
- shortage of local technical support, spare parts, accessories or consumables;

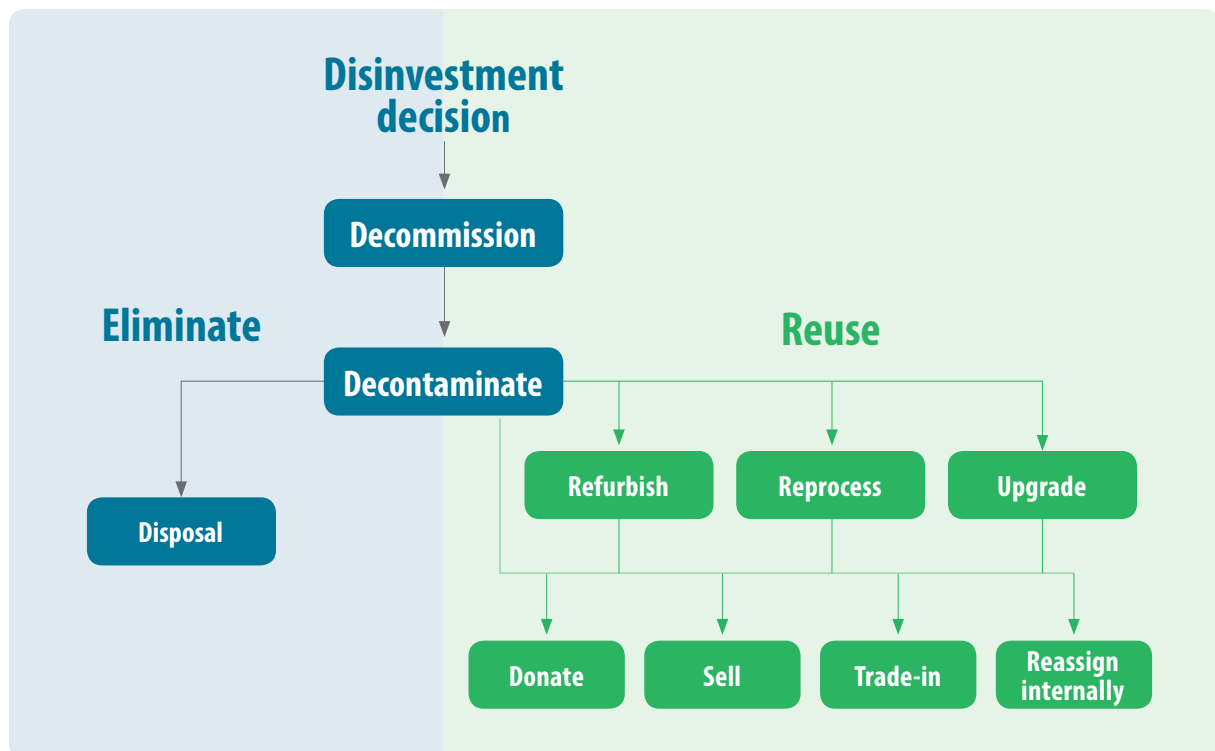


Fig. 2. Decommissioning medical devices

- infrastructure incompatibility (e.g. the device must be connected to a network in order to provide electronic health records or for another purpose, but this is not technically or financially feasible);
- serious concern about unreliable cybersecurity (for networked devices); and
- a catastrophic event (such as an accident, emergency or disaster) that may compromise the functioning of the device.

Factors related to administrative or policy-level decisions are:

- high maintenance costs,
- regulatory withdrawal of a medical device from the market,
- availability of new, more expensive or clinically effective technology,
- standardization (limiting the number of models of a particular device) and
- clinical or technical obsolescence.

Incorrect classification for decommissioning includes deciding that a medical device is obsolete once a new model is released onto the market. As discontinued devices are usually fully supported by their manufacturers and third-party sources for several years, the availability of a new model should not necessarily lead to decommissioning. Only when the vendor or provider no longer services a medical device, should decommission and purchase of the new version be considered. The requirement for a medical device should be appropriately assessed before a decision to decommission is made.

It is essential to correctly determine the end status of a medical device after it has been decommissioned to ensure proper management, reduce waste and minimize the risk of harmful exposure of personnel, the public and the environment. In this section, we explore various aspects of decommissioning of medical devices, including risk auditing, personnel, infrastructure preparation, decontamination, patient data management, waste management, inventories and reporting.

3.1 Implementation

The steps in decommissioning medical devices depend on the option chosen: disposal, donation, sale, refurbishing or reprocessing, trade-in or internal reassignment. First, risk and cost should be assessed to determine the best course of action in relation to the personnel and infrastructure available. The next stage is to ensure that the device is safe for handling and treatment or removal, by cleaning and decontaminating it, removing patient data, disposing of consumable parts and (if relevant) withdrawing or removing its listing from the paper-based or computerized inventory. In a final step, the preceding stages and the end status of the device should be documented in a report for future reference. The administration of the health facility may require a “decommissioning document” in order to remove the device from the asset registry.

3.2 Risk auditing and cost assessment

Any risks related to decommissioning should be assessed. Consideration should be given to the health and safety of patients, the public, the environment and health care workers. A comprehensive plan should be outlined for the mitigation, transfer or monitoring of any risk.

The cost of decommissioning medical devices is determined by the process and technology used. Costs such as site modification, equipment and accessories, disassembly, removal and shipment should be considered. The costs may include labour, consumables, utilities, repair, maintenance, personal protective equipment, training and insurance. The differences in the costs of various decommissioning options could be analysed to decide on the device’s end status and determine which option is most beneficial.

3.3 Personnel

Decommissioning personnel are responsible not only for proper, safe decommissioning but also for assessing risks and cost. Guidance on decommissioning should be provided for seven main categories of personnel:

- managers and regulatory staff;
- safety officers, biomedical engineers, medical physicists, radiographers, biomedical laboratory scientists and other staff involved in medical device management;
- medical doctors;
- nurses;
- cleaners;
- waste handlers and drivers; and
- store, purchase and accounts officers.

All should be involved when a device requires their expertise on decommissioning. Safety officers play an important role in ensuring that decommissioning is conducted appropriately without causing harm to the environment, the public or health care workers.

Every health care institution should have standard operating procedures on waste, including the roles and responsibilities of health care workers in waste management, and technical instructions on their application. When hazardous material is involved, personnel must be provided with appropriate personal protective equipment, including face shields, barrier gowns or impervious aprons, gloves, masks and protective footwear.

To ensure safe decommissioning of medical devices, personnel should be qualified, trained and competent in the processes to minimize incidents that may harm them, the public and/or the environment.

3.4 Infrastructure

Infrastructure may not have to be prepared for decommissioning smaller devices; however, it is essential when decommissioning large

devices such as computed tomography scanners, linear accelerators, X ray machines, magnetic resonance imaging scanners and steam sterilizers. Appropriate people should be consulted, such as a qualified contractor, department manager, facility manager or the original manufacturer, to ensure safe removal of the device.

As medical devices are often large and heavy, special equipment may be required for transport, and a passage might have to be reinforced or widened or a wall destroyed to take out bulky equipment. Large devices often consist not only of the device itself but also of equipment such as screens, cameras and other components. All these elements must be considered in decommissioning the main device. The time required to decommission a large device should also be taken into consideration and planned, consulted with the equipment planner in close collaboration with the staff of the unit, so that their daily schedules are coordinated with the decommissioning. In some cases, protection and signalization for patients must be foreseen.

For medical devices containing hazardous material, emergency equipment must be functional, accessible and available. Equipment such as fire extinguishers, eye wash, emergency showers, ventilation and spill kits may be necessary. Consideration should also be given to potential escape of helium gas. Experienced contractors may be required to decommission higher-risk medical devices.

3.5 Decontamination of devices

Decontamination is required for decommissioning both single-use and reusable medical devices. Figure 3 illustrates the salient features of decontamination, each step of which is as important as the next. Further information about decontamination can be obtained from a comprehensive WHO guide on decontamination and reprocessing of medical devices for health care facilities (19).

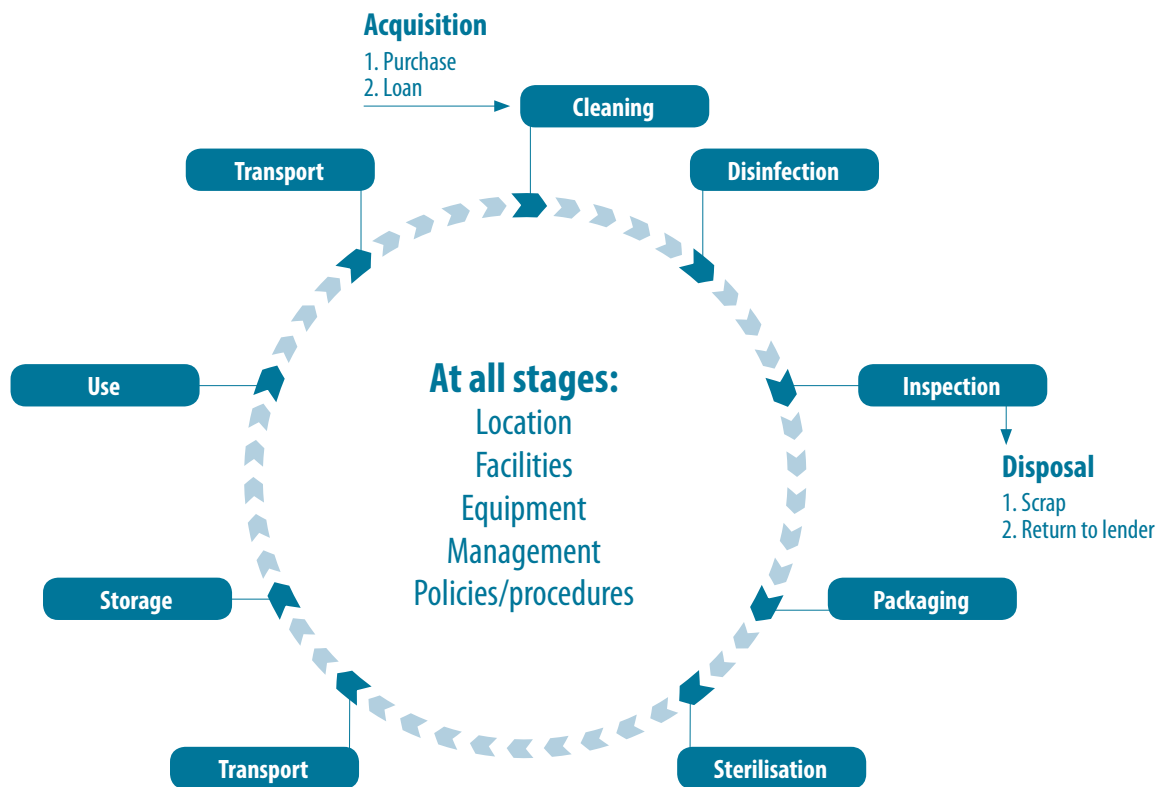


Fig. 3. Decontamination life cycle

Source: (20)

All used or potentially used medical devices must be cleaned, as in the instructions specific for the device or type of device. The basic steps in cleaning and disinfection that are included in most instructions are as follows.

1. **Disassemble.** The device should generally be disassembled and sorted. Any consumables and sharps must be removed and properly disposed of according to health care waste management procedures.
2. **Clean.** The device should then be cleaned with a compatible cleaning agent such as a detergent (alkaline or pH neutral) or enzymatic solution. It should be submerged in water and rubbed, scrubbed or brushed to remove air pockets and prevent aerosolized transmission of infection. As not all devices can be submerged in water, it is imperative to follow the instructions. Once the device has been cleaned of debris, it should be thoroughly rinsed with detergent and inspected.
3. **Manual cleaning.** Grossly soiled devices should be cleaned manually before being processed in a mechanical washer. If an automated washer is unavailable, manual cleaning steps, as outlined in the instructions, should be followed.
4. **Mechanical cleaning.** Mechanical washer–disinfectors and ultrasonic washers increase the effectiveness of cleaning. They are designed to remove microorganisms by cleaning and rinsing thermally or chemically and/or cavitation.
5. **Disinfect.** Devices that are not intended for immediate reuse (e.g. for relocation, trade-in, donation or disposal) should, at a minimum, be thoroughly disinfected thermally or pasteurized after thorough cleaning. Sterilization is recommended and preferred for complete removal of microorganisms.

3.6 Removal of patient data

Patient data and information stored in medical devices should be erased or removed by the person responsible for the information before a medical device is decommissioned (regardless of its end status) to protect sensitive information and patient confidentiality. If the device is identified for disposal, media sanitation may include destruction of confidential data and software registered to that device. Medical devices believed to contain data can be sent to a biomedical or clinical engineer who can use proven procedures to erase the data thoroughly.

If the device is configured to cloud storage, the IP pathway connecting the device to the cloud needs to be deactivated. Additionally, the data stored on the cloud of the device needs to be either deleted or made part of the Electronic Record System such that access to such data including images captured by the device (now planned for decommissioning) is either preserved by another pathway or deleted. This would eliminate the probability of data loss or data misuse once the device has been decommissioned.

3.7 Waste management

Sound health care waste management ensures safety and minimal effects on health care workers, the population and the environment. A comprehensive system should include:

- waste generation and minimization;
- separation and segregation of sources;
- identification and classification of wastes;
- handling and storage;
- packaging and labelling;
- transport on site and off site;
- treatment;
- disposal of residues (including emissions);
- consideration of occupational, public and environmental health and safety;
- stakeholder and community awareness and education; and

- research and development of improved technologies and environmentally friendly practices.

A waste management system can be integrated into an environmental management system for enhanced documentation, auditing and practices. More information on the management, treatment and disposal of waste is available in the WHO publication *Safe management of wastes from health-care activities (2014)* (21) and Annex 1 to this document.

3.8 Inventory system and decommissioning report

Decommissioning of every medical device should be documented and reported. Once the device has been disposed of, donated, sold or traded-in, the next step is to remove the listing of the device from the inventory database or archive it. In the case of internal reassignment or reprocessing, the inventory must be updated. The information to be included in the decommissioning report might include the:

- date and/or period of decommissioning;
- type of medical device;
- original location (such as laboratory, general ward, intensive care unit);
- condition of the device before decommissioning;
- reasons for decommissioning;
- decommissioning process;
- end status of the device;
- cost of decommissioning;
- value of the device if sold or traded-in; and
- personnel involved in decommissioning.

3.9 Further reading

ISO 17664. Sterilization of medical devices – information to be provided by the manufacturer for the processing of resterilizable medical devices. Geneva: International Organization for Standardization; 2004.

ISO 14971. Medical devices – application of risk management to medical devices. Geneva: International Organization for Standardization; 2007.

Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ST79). Arlington (VA): Association for the Advancement of Medical Instrumentation; 2010.

ISO 13485. Medical devices – quality management systems – requirements for regulatory purposes. Geneva: International Organization for Standardization; 2016.

WHO has released other relevant guidance, including:

- Rapid guidance on decommissioning of Ebola care facilities. Geneva: World Health Organization; 2015.
- Checklist for terminal cleaning and decontamination of Ebola care facilities. Geneva: World Health Organization; 2015.
- World Health Organization, Pan American Health Organization. Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016.



4. Disinvestment

Disinvestment is the withdrawal of resources in a health care service when there is evidence that they are clinically ineffective, unsafe, inappropriate or not cost-effective (22). Disinvestment is intended to be beneficial to patients, clinicians, administrators and payers, rather than simply a means of eliminating health care services for the purpose of saving money. A decision to disinvest may result in decommissioning. As decommissioning often requires significant resources and time, disinvestment must be systematic and structured. In this section, we present four stages that characterize disinvestment.

4.1 Stages of disinvestment

Disinvestment typically involves four stages: identification, context-specific prioritization, implementation and impact evaluation (Fig. 4). A toolkit that provides step-by-step guidance to health care organizations and governments that are contemplating withdrawing resources associated with a health care service will be available on the website of Health Technology Assessment International (23). Highlights of the stages are presented in this section.

4.2 Identification

The first stage involves identifying technologies for disinvestment. Candidates for disinvestment may be found incidentally during assessment of the allocation of financial and human resources

within a health care system or by detection of variation in the use or clinical effectiveness of services and their attendant devices access in several health care facilities. Disinvestment candidates may also be identified during proactive appraisals of new devices being considered for procurement, by a comparison of safety and costs, or after the introduction of clinical practice guidelines that require changes to procedures that involve medical devices.

Exercises in financial and human resource allocation are generally conducted at the level of health service delivery, when decisions are made about the appropriate use of available resources. Candidates for disinvestment may become apparent when new restrictions are placed on resources or when additional resources become available to acquire technologies that are suitable replacements for those in use. Disinvestment may also be considered when the administrators of a health care system receive information about geographical and temporal variation in the frequency of use or effectiveness of a technology in their network (24). An appraisal of new health technologies might indicate their advantages over existing technologies; or adoption or revision of clinical practice guidelines and consultation with clinicians or clinical experts may result in identification of candidates for disinvestment (25). For instance, members of medical specialty societies involved in the “Choosing Wisely” campaign create lists of tests and procedures considered to be ineffective, unsafe, overused or propagating health inequalities in clinical practice according to explicit guidelines (26,27).

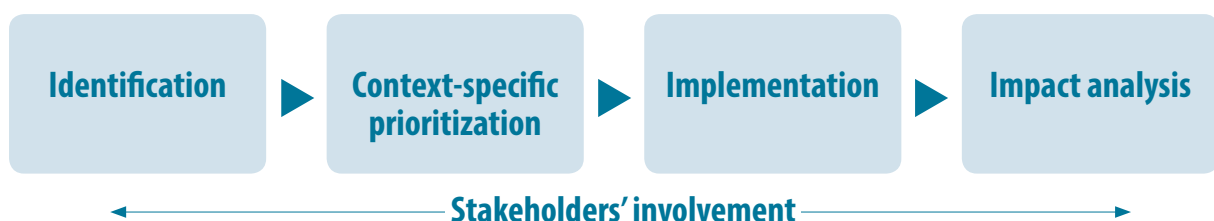


Fig. 4. Stages of disinvestment

Devices used to conduct these tests and procedures are those considered candidates for disinvestment.

4.3 Context-specific prioritization

Not all candidate technologies progress to disinvestment. Prioritization of candidates for disinvestment is systematic and is ideally conducted across a healthcare system. It requires ranking of identified candidates by centring on the organizational impact and the context in which a change in a health service is being contemplated. Ranking also incorporates costs or budget impact, cost–effectiveness, net economic value or value for money and the preferences and perspectives of patients and clinicians (28). Consideration may also be given to use of the technology in its context, variation in and the adequacy of current practices, local health improvement goals, organizational resilience, programmed obsolescence and environmental impact. The ranking of disinvestment candidates is also guided by whether the candidates are prioritized at departmental, organizational or national level, which may have different interests (29) and therefore different priorities. For example, at departmental level, there may be conflicting priorities and insufficient engagement among stakeholders, lack of authority to make changes, external societal and political influences, complex health care delivery pathways, resistance to change, vested interests, asymmetrical information among stakeholders and well-established interest and advocacy groups. The national level has the authority to make change but may be at some distance from where technologies are used. Understanding where priorities are set and the factors that guide decisions at that level is critical to the next stage of disinvestment, implementation.

4.4 Implementation

Implementation requires well-structured, defined processes. Published guidelines, such as the Guideline for Not Funding Existing Technologies of the Basque Office for Health Technology Assessment in Spain (30) and the

Health Technology Performance Assessment published by the National Committee for Technology Innovation in Brazil (31), include strategies for facilitating disinvestment decisions. Implementation can also be driven by partnerships among clinicians, patients and administrators. Endorsement may be assured by aligning disinvestment initiatives with the goals and objectives of leaders. Moreover, collaboration with administrators and payers can help clinicians and patients focus on the benefits of disinvestment, such as equitable distribution of resources, quality, continuous improvement and system-wide cohesion (32). Evidence-based research and operational protocols can further strengthen implementation of disinvestment decisions.

4.5 Impact analysis

After a decision has been made to disinvest in a health technology, it is important to assess whether the change had the anticipated effect on delivery of care. Impact analysis indicates whether disinvestment helped health care administrators, clinicians and patients to attain their goals. Published evidence suggests that most impact analyses of disinvestment decisions have been conducted to assess financial savings rather than clinical impact (25,27). Ideally, the analyses would include an assessment of changes in health outcomes, equity, safety, organizational aspects, the environment and social outcomes. For example, greater clinical effectiveness, reduced numbers of adverse events, wait times and medical waste, and better patient quality of life are all practical indicators of the impact of a disinvestment decision.

4.6 Summary

A decision to disinvest may mean complete removal of a service and subsequent decommissioning of a medical device. The timing of decommissioning should be analysed to ensure that the system can withstand the proposed change with no long-term negative effects on health care delivery. Irrespective

of the framework, methods and tools used to decide on disinvestment, the four stages of disinvestment are commonly identification, context-specific prioritization, implementation and impact analysis. Candidate devices for disinvestment can be identified and prioritized by several approaches, such as an assessment of available financial and human resources, published syntheses of evidence from several locations, assessment of differences in use of a health care service at several facilities and new clinical practice guidelines. A systematic, structured process can guide implementation of a disinvestment decision and ensure that the objectives of clinicians, patients and administrators are met. A “disinvestment

toolkit” is being prepared by Health Technology Assessment International and the EuroScan Network, which will provide comprehensive guidance to health care organizations and governments, including WHO Member States, that are seeking to disinvest (23).

4.7 Further reading

Calabro et al. Disinvestment in healthcare: an overview of HTA agencies and organizations activities at European level. BMC Health Services Research 18, Article number: 148 (2018). (<https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-2941-0>)



5. Single-use medical devices

Single-use medical devices (SUMDs), also referred to as disposable devices or single-use devices (SUDs) according to the Food and Drug Administration (FDA), are intended to be used on one patient during a single procedure. They are not intended to be reprocessed (cleaned, disinfected or sterilized) or used on another patient. The labelling may include a characteristic symbol for single-use products (Fig. 5) and no instructions for reprocessing. Health care practitioners are opting for single-use devices that provide optimal performance without the risk of cross-infection associated with reusable devices that are difficult to clean, disinfect and sterilize.



Fig. 5. Harmonized symbol for single-use products

Source: (33)

5.1 Disposal

Disposal of medical devices includes intentional burial, deposit, discharge, dumping, placing or release of any waste material into or on air, land or water. For radioactive waste, disposal is placement of waste in an approved, specified facility (e.g. near-surface or geological repository) or approved direct discharge into the environment. Disposal is undertaken without the intention of retrieval. It includes the pre-stages of disassembling medical devices for recycling.

Single-use devices should be disposed of in such a way as to ensure the highest standard of patient safety. (See also section 6.6.)

5.2 Reprocessing

Reprocessing of medical devices comprises all the steps in making a contaminated device reusable or a single-use device “patient-ready”. The steps are decontamination, cleaning, drying, functional testing, repackaging, relabelling, disinfection and sterilization.

As SUMDs are designed for use on an individual patient during a single procedure, they do not come with appropriate instructions for cleaning, disinfection or sterilization after use, and the manufacturer has not investigated whether their safety and performance deteriorates if they are reprocessed. SUMDs that have been reprocessed and used more than once may therefore be dangerous for patients, as conformity to the original standards for their safety, quality and performance cannot be assured. The potential health risks associated with reuse of SUMDs are:

- possible cross-infection because of the impossibility of assuring complete removal of viable microorganisms without validated instructions for cleaning and sterilization;
- inadequate cleaning, decontamination and removal of pyrogens and material alteration;
- changes in properties or degradation of the device material due to repeated sterilization;
- absorption of residues of chemical cleaning agents by the material of the device that leak from the material over time, resulting in exposure of patients or users;
- corrosion or changes in the materials of the device due to exposure to chemical cleaning agents; and
- impairment of the quality of devices by the high temperatures and harsh chemicals sometimes used during reprocessing.

Ethical considerations are also associated with use of reprocessed SUMDs, in addition to the potential health risks. They include whether it is justifiable to treat a patient with a reprocessed SUMD that may be of poorer quality, performance, safety or cleanliness than when it was used for the first time, even with informed consent. Other considerations include liability, as the entity that reprocesses a medical device becomes the new “manufacturer”, with the associated responsibilities. They also include economic considerations, as reprocessing of a SUMD with a validated process raises the cost. In addition, for some medical devices, a relevant percentage of units that undergo the reprocessing process may not reach the state at which the necessary conditions to be safely and adequately reused are met, being lost to the reprocessing process. Therefore, the perceived savings may not be attained. Consequently, reprocessing and reusing SUMDs is not advised.

Additional research is required to investigate the safety of reusing SUMDs. As stated in the WHO Global model regulatory framework for medical devices (6), WHO recommends that regulatory authorities at national, jurisdictional and facility levels adopt a policy on reprocessing and reusing SUMDs. In doing so, they should consider that a reprocessed SUMD cannot be labelled with its original name unless it meets the same standards as those of the original manufacturer. To reuse devices, the entity that reprocesses and distributes those labelled by their original manufacturer for single-use only will be subject to the same requirements for safety, quality and performance as the manufacturers of new devices. This also applies to health care facilities that fully reprocess SUMDs for internal reuse.

Australia, Canada, Israel, the Republic of Korea, Saudi Arabia and the European Commission have advised against or prohibited reprocessing of SUMDs or have recommended enforced conformity to the regulations for medical device manufacturers as a minimum standard. Many countries, however, have little or no regulatory, medical, legal, economic or ethical guidance on the practice.

Despite these considerations, reuse of SUMDs has increased as a cost-saving measure. To address this practice, the US Food and Drug Administration issued guidance for facilities that choose to reprocess single-use devices (34), in which the US Centers for Disease Control and Prevention and the International Association of Healthcare Central Service Materiel Management provide reference and support. These recommendations do not cover health care facilities other than hospitals, implantable devices (see section 7.6), haemodialysers or opened but unused SUMDs.

The process used by the US Food and Drug Administration is as follows.

- The device shall be classified according to its risk classification (Table 1).
- The reprocessor can demonstrate that the SUMD can be adequately cleaned and disinfected or sterilized and that the characteristics or quality of the device will not be adversely affected by these processes.
- The party or facility that reprocesses a single-use device becomes the manufacturer of the device and is responsible for ensuring that it is safe and effective for reuse after reprocessing. As the manufacturer of the reprocessed single-use device, the party or facility shall adhere to premarket requirements and regulations.
- A tracking system shall be in place to enable prompt location of devices for recall in the event that corrective action or notifications to the device is necessary.
- Correction or removal of a device shall be reported to the regulating body. It may be removed for repair, modification, adjustment, relabelling, destruction or inspection.

Parties (such as a health care facility or third-party reprocessor) are subject to the same regulatory and reporting measures as the original manufacturer of the SUMDs they reprocess. As exposure to reused SUMDs may be unsafe for patients, the liabilities related to the SUMD fall on the party who reprocesses the SUMD. The US FDA has published a list of SUDs (which

Table 1. Examples of medical devices by risk class

Class	Risk	Examples
A	Low	Syringes, examination gloves, patient hoists, stethoscopes, wheelchairs, IVD diagnostic instruments, microbiological culture media
B	Low–moderate	Surgical gloves, infusion sets, pregnancy tests
C	Moderate–high	Condoms (except with spermicide, high risk), infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, haemodialysers, anaesthesia equipment, self-test glucose strips, IVDs for diagnosis of gonorrhoea
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, angioplasty balloon catheters, spinal needle, IVDs for diagnosis of HIV infection, hepatitis C or hepatitis B

Source: (6)

are FDA equivalent to SUMDs) known to be reprocessed.

The risk class of a medical device is determined by factors such as the degree of invasiveness, the anatomical location as well as the duration of use in the body. In some jurisdictions, products such as viral inactivation devices used in the manufacture of medicinal or biological products are deemed to be higher-risk medical devices and are regulated accordingly. It is widely accepted that medical devices can be separated into groups or classes, often labelled A, B, C and D (Table 1).

Accurate classification of devices is critical for the safety of patients and users. The instructions for use and the intended use of the device should be consulted.

5.3 Further reading

Scientific Committee on Emerging and Newly Identified Health Risks. The safety of reprocessed medical devices marketed for single-use. Brussels: European Commission; 2010.

Single-use medical devices: implications and consequences of reuse. London: Medicines and Healthcare Products Regulatory Agency; 2013.

International regulation of “single-use” medical device reprocessing, Washington DC: Association of Medical Device Reprocessors; 2014.

US Food and Drug Administration. Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data; 2005.

World Health Organization and Pan American Health Organization. Decontamination and reprocessing of medical devices for health-care facilities. Geneva: World Health Organization; 2016.

6. Reusable medical devices

A reusable medical device is designed to be used on more than one patient. The final status of decommissioned reusable medical devices may be disposal, donation, sale, trade-in, internal reassignment, refurbishment or an upgrade. All devices must be decontaminated before any of these actions.

6.1 Reassignment

Reassignment of a medical device is its transfer internally or externally to another unit or facility that requires it. Internal reassignment of a medical device refers to its transfer within the health care system.

When the performance of the device is still acceptable and reliable, its relocation to another department that needs it may be considered. It is essential to determine whether the device qualifies for reuse on the basis of a lower acuity application, availability of training, maintenance and other resources.

Examples of reassignment are:

- relocating a patient monitor from an emergency department to a general ward;
- relocating devices to a biomedical department for reuse as substitutes or spares; and
- recycling parts and modules that function properly and have a viable application in existing systems. This is sometimes termed “cannibalization” and is often done by biomedical technicians to ensure a source of spare parts and modules, which is valuable in locations where parts are difficult and expensive to procure. In the case of circuit boards, close attention is required to part numbers and software revision to ensure compatibility with existing systems.

Communication between the donor and recipient is critical to ensure that needs are met,

infrastructure is set up, medical and biomedical human resources, material resources, financial resources and the medical market are available, and transport is coordinated.

For a few medical devices, a partial decommissioning of an important component could lead to reassignment. Such situations arise when:

- the part to be decommissioned is a major portion of the cost of the device;
- has a life span very different from the life of the device; or
- the part in itself is irreparable but replaceable.

E.g. CT Scan or X-ray tubes may require part decommissioning as the lifespan of the tube could be much lesser than the device itself. It cannot be repaired but can be replaced and forms a substantial cost of the entire device. The guidance provided in this document should also be applied to such ‘partially decommissioned part’.

6.2 Refurbishing

Refurbishing consists of reconditioning used medical devices with no significant change in their performance, safety specifications or service procedures as defined by the manufacturer and its original intended use. Refurbished medical devices should be labelled as such. In a policy on refurbishing, the regulatory authority should clearly state that the entity responsible for refurbishing or the third party must meet the same regulatory requirements as applied to the original medical device. A party that refurbishes medical devices will be subject to the same requirements of safety, quality and performance as manufacturers of new devices (6).

As for any medical device, the manufacturer’s instructions for use should be followed. If there

are no validated instructions, they should be obtained from the supplier or manufacturer. Copies of users' and maintenance manuals should be available and accessible to personnel and updated as required. National regulations on medical devices should also be consulted, as certain countries restrict use of refurbished medical devices.

If the medical device has been determined to be safe for reuse by the national regulatory authority, it must be decontaminated, cleaned, dried, tested for functionality, repackaged, relabelled, disinfected or sterilized before it is returned to service. The steps in refurbishing depend on the validated instructions provided by the manufacturer and the risk of infection posed by the devices, as listed in Table 1. For example, "B class" risk devices should be ideally be thoroughly cleaned and decontaminated and then sterilized, thermally disinfected or pasteurized, while "critical devices" should be thoroughly decontaminated, cleaned, dried, re-packaged and relabelled before sterilization. Steam sterilization is the preferred method because of its cost-effectiveness and availability. Devices that cannot withstand heat can be sterilized chemically with hydrogen peroxide, ethylene oxide, peracetic acid or ozone as per the manufacturer's written instructions. To minimize and prevent damage to devices, they should be handled in small lots. Items with sharp edges should be protected to prevent damage and harm to the user, while delicate items should be separated from heavy items and protected to prevent damage.

To reuse a medical device, after formal approval, the following refurbishing steps are recommended:

1. Ensure that validated cleaning and sterilization instructions from the manufacturer are included with reusable medical devices.
2. Follow the validated cleaning process.
3. Conduct regular in-house maintenance and inspection for functionality, damage and cleanliness.
4. Keep a current record of the maintenance and inspection of reprocessed devices.
5. Conduct the decontaminating or sterilizing procedures as in the instructions.
6. Once the device has been decontaminated and/or sterilized and all other instructions have been followed, it can be reused.

If the device is not required immediately, it should be stored in a clean, dry, protected area. Devices should be stocked in rotation according to the first-in, first-out principle and separated from other items by barriers and/or distance. Refurbishment is considered an effective way of preventing waste and saving resources and energy, as it may prolong the effective working life of medical devices. When a device can be refurbished, it is a more economical alternative to purchasing a new one; however, not every medical device can be refurbished, and careful assessment and selection criteria must be used. The five-step refurbishing process recommended by the Global Medical Imaging Industry (35) is shown in Figure 6.



Fig. 6. Five-step refurbishing process

Source: (35)

1 Selection of equipment for refurbishment

- Devices are selected for refurbishing on the principle that, at a minimum, they will have the same quality, performance, safety and intended use as when they were new.
- Common reasons for disqualification from refurbishment include not meeting adequate safety or performance standards, having reached its lifetime, is a single-use device or was not intended for refurbishment.
- Other considerations include compatibility, upgradability, working life, availability of spare parts or components, after-sales service, maintenance and serviceability.

2 Disassembly, packaging and shipment

- Personnel with assigned responsibility should perform procedures such as removing patient data, cleaning and disinfecting and removing the device from the tracking system or inventory.
- Clear shipping instructions should be documented before the medical device is sent for service.

3 Refurbishment

- Medical devices should be refurbished by an authorized party, such as the original manufacturer of the device or a third-party facility with the requisite technical expertise.

4 Reinstallation of equipment

- Health care facilities should establish clear communication with the party that services their medical devices.

5 Professional services

- The after-sale service and support to be provided by the refurbisher should be determined.
- The services should include warranty, spare parts, maintenance contracts, updated management, user training, service contracts and product support.

6.3 Donation

“Donation” refers to designating a medical device as an aid, generally free of charge for the recipient. Medical devices can be donated when the safety and performance conditions can be met. The WHO guidelines on medical device donations (36) are summarized below and should be consulted for more information.

For example, a hospital may consider donating medical equipment directly to a low- or middle-income country hospital or to a specialized nongovernmental organization, usually as an exchange, which will be responsible for preparing the equipment for re-use and assigning it to a health facility that needs it and that has sufficient capacity and means to use the device wisely. Medical devices should be cleaned and disinfected before being donated to remove any source of cross-contamination. Many low- and middle-income countries rely on donations because of financial constraints; however, a number of considerations should be reviewed by all the parties involved before a donation is made.

- There must be clear communication between the donor and the recipient before, during and after the donation by all means available to ensure active, responsible involvement of both parties and mutual benefit.
- The donor should provide the history and documentation of the device and all available information on its condition to guide recipients in installing, using and maintaining the donated material, especially electrical and electronic medical equipment.
- The recipients should be involved in all stages of donation:
 - › prioritizing donor offers according to their needs and capacity (e.g. access to water, stable electrical supply);
 - › adhering to local and international policies on donating, exporting and importing medical devices;
 - › ensuring safe delivery; and
 - › providing feedback to the donor.

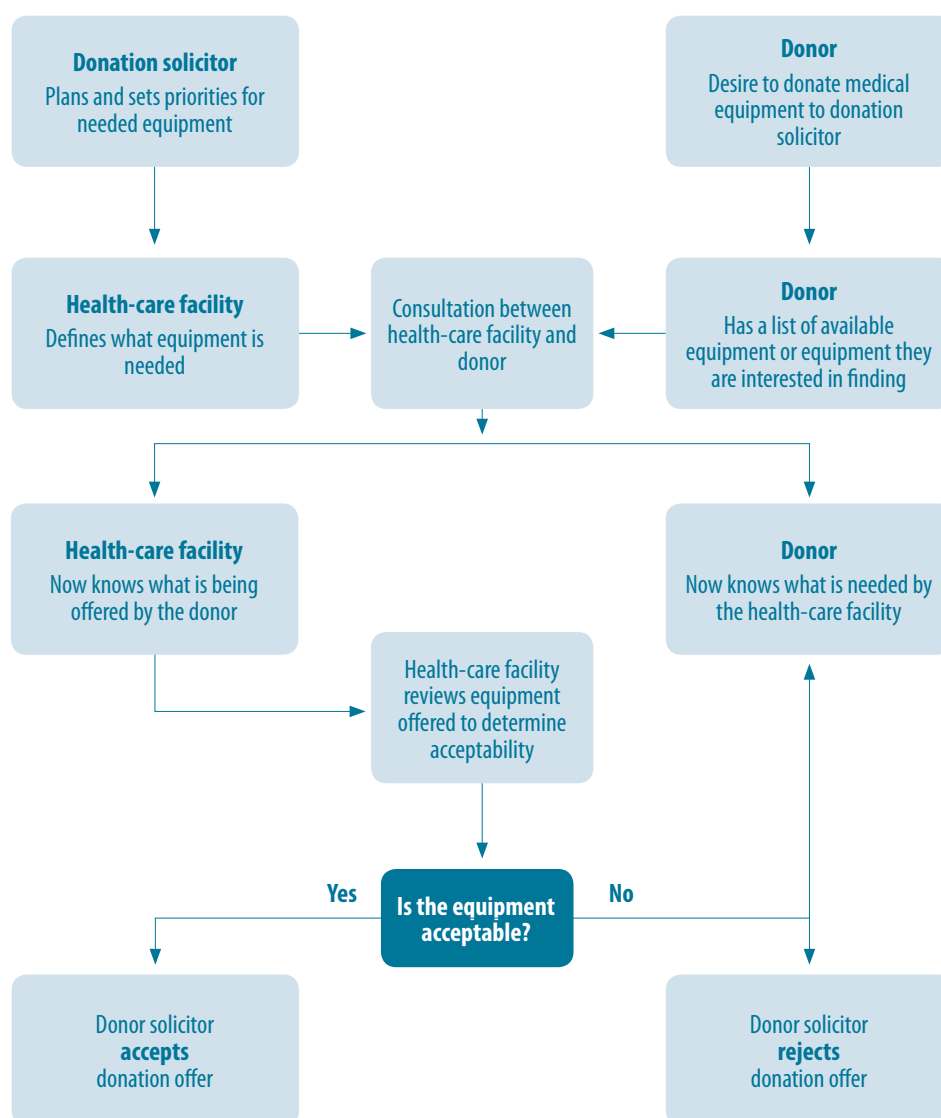


Fig. 7. Soliciting and offering donations of medical equipment

Source: (36)

- The needs of the recipients and patients should be considered and fulfilled by donations.
- International and national regulations for medical device donation should be followed by both donors and recipients.
- Proper installation in the building or room, relevant protection of staff, patients and the public (e.g. radiation equipment), user training, inventory and regular preventive maintenance by both the user and clinical engineers should be completed when the donation is received by the recipient.

If the recipient cannot afford installation, services and supplies, donations to cover those expenses should be considered. The steps illustrated in Figure 7 provide guidance on deciding whether a proposed donation is acceptable.

To ensure the availability of consumables, parts and support for service, a local medical equipment service provider should be engaged, if available. The donation may be made within the country or from abroad, and both donors and recipients should adhere to the regulations for exporting and importing medical devices.

For instance, European donors of second-hand electrical and electronic medical devices must comply with the Directive of the European Parliament and of the Council on waste electrical and electronic equipment (37) and specifically its Annex VI, “Minimal requirements for shipment”, which imposes important obligations, such as providing written proof of equipment evaluation and proper functioning, in order to prevent shipment of faulty equipment.

6.4 Sale

Decommissioned medical devices can be transferred within a jurisdiction or sold to another health care facility that needs them, in accordance with the regulations in force. When a medical device is intended to be sold as a second-hand device to a health care facility in a lower-resource setting (even in the same jurisdiction or country), reuse, training and maintenance must be compatible with local infrastructure and resources, in parallel to the donation. Decree No. 2011-968 of 16 August 2011 on the resale of second-hand medical devices in the French Public Health Code, for instance, states that the person responsible for the sale of certain second-hand medical device (list determined by order of the Minister of Health) is obliged to draw up a prior technical certificate that the medical device has been maintained regularly. The certificate should also mention the indications necessary for identifying the medical device and the date of first commissioning or, if the device has never been used, the date of first acquisition. Attention should also be paid to the safe transport and delivery of the device in comparison with an internal relocation. More information is available in the WHO guidelines on medical device donations (36).

6.5 Trade-in

Some medical devices are procured on a lease or on loan. “Trade-in” refers to returning medical devices to a vendor at a predetermined value towards the purchase of a new device or upgrade. This service is particularly useful for

devices that require intensive maintenance or rapid technological upgrades. The cost–benefit of a trade-in service should be considered and calculated at the time of procurement. The benefits of establishing a trade-in plan with a medical device supplier generally include:

- removal and decommissioning of the device by the supplier,
- a new or upgraded device to better serve the user’s needs and
- economic benefits of an established relationship with the supplier.

When a device reaches the end of its useful working life, becomes obsolete or is damaged, it may be eligible for replacement. It is important to check the service and warranty terms and conditions before contacting the device supplier. Often, a device can be traded-in for an equivalent replacement or an upgrade with a revised lease agreement. Alternatively, an agreement may be established with another supplier who will take responsibility for removing and decommissioning the existing device after procurement of a new one.

6.6 Disposal

The disposal of medical devices includes intentional burial, deposit, discharge, dumping, placing or release of waste material into or on air, land or water. In radioactive waste management, waste is placed in an approved, specified facility (e.g. near-surface or geological repository) or discharged directly into the environment. Disposal is undertaken without the intention of retrieval. It includes disassembling the medical device for recycling.

Items should be reused and waste minimized when safe and practical. Disposal of untreated health care waste in municipal landfills is not advisable. Depending on the infrastructure

Table 2. Health care waste categories

Waste category	Description and examples
Hazardous	
Sharps	Used or unused sharps (e.g. hypodermic, intravenous and other needles, auto-disable syringes, syringes with attached needles, infusion sets, scalpels, pipettes, knives, blades and broken glass)
Infectious	Waste suspected of containing pathogens that poses a risk of disease transmission (e.g. waste contaminated with blood and other body fluids, laboratory cultures and microbiological stocks and waste including excreta and other materials that have been in contact with patients with highly infectious diseases in isolation wards)
Pathological	Human tissues, organs or fluids (e.g. body parts, fetuses and unused blood products)
Pharmaceutical, cytotoxic	Pharmaceuticals that have expired or are no longer required and items contaminated with or containing pharmaceuticals; cytotoxic waste containing genotoxic substances e.g. waste containing cytostatic drugs and genotoxic chemicals)
Radioactive	Waste containing radioactive substances (e.g. unused liquids from radiotherapy or laboratory research, contaminated glassware, packages or absorbent paper, urine and excreta from patients treated or tested with unsealed radionuclides and sealed sources)
Electronic waste	Waste containing electronic components and parts (for e.g. batteries, printed circuit boards, embedded electronic parts, piezoelectric crystals etc.)
Non-hazardous	
General health care	Waste that does not pose a biological, chemical, radioactive or physical hazard

Source: (21)

available at the health care facility, treatment and disposal can be carried out on site by trained personnel or off site by a reputable party experienced in managing health care waste. Waste produced from health care activities can potentially cause infection and injury. Safe, reliable management of health care waste is essential to protect health care workers, public health and the environment, and WHO has issued a handbook on this topic, *Safe management of wastes from health-care activities* (21).

6.6.1 Waste categorization and segregation

Health care waste is categorized as either hazardous or non-hazardous. Health care personnel must be trained in procedures for managing all types of medical device waste (Table 2).

6.6.2 Treatment and disposal

Medical devices should be sorted according to treatment and disposal requirements, taken from the source of waste (i.e. the ward, operation theatre, laboratory, bedside) and disposed of by the health care worker who generated the waste.

Medical devices must then be treated to reduce potential health and environmental hazards. The treatment method is selected on the basis of the following considerations:

- type and quantity of waste for treatment and disposal,
- capability of the health care facility to handle the quantity of waste,
- local availability of treatment options and technologies,
- treatment technology and requirements,
- skill in using the technology,
- volume and mass reduction,
- installation requirements and costs,
- availability of space for equipment and infrastructure,
- operation and maintenance requirements,
- environmental and safety factors,
- location and surroundings of the treatment site and disposal facility,
- occupational health and safety,
- public acceptability,
- options for final disposal,
- regulatory requirements,
- equipment purchase cost,
- shipping fees and customs duties,

- annual operating costs, including preventive maintenance and testing,
- cost of transport and disposal of treated waste and
- cost of decommissioning.

In view of these considerations, medical devices should undergo thermal, chemical, radiation, biological or mechanical treatment. For hazardous (infectious) waste, disinfection or sterilization is required to minimize potential disease transmission. The most common treatments for infectious waste are:

- steam treatment (autoclaving),
- integrated steam treatment (hybrid autoclaves or advanced steam treatment),
- microwave treatment,
- dry heat treatment,
- chemical treatment (internal shredding or chemical disinfectants) and
- incineration (combustion, pyrolysis or gasification).

These can be supplemented by shredders, grinders and compactors. Treatment and disposal methods for medical devices containing sharps, mercury, radionuclides and chemicals are covered specifically in section 7.

6.6.3 Land disposal

After treatment is completed, land is required for disposal of medical devices. Uncontrolled dumping is characterized by scattered deposition of wastes that can lead to acute pollution, fires, high risks of disease transmission and open access to human and animal scavengers. Health care waste should not be deposited on or around uncontrolled dumps. Controlled landfilling involves use of practices and improved design to reduce impacts on health and the environment. In addition to treatment

of waste before disposal, better engineering standards are used to ensure geological isolation of waste from the environment and to ensure that they are covered daily. Engineered landfills are intended to:

- minimize contamination of soil, surface water and groundwater;
- limit atmospheric releases and odours;
- block access to waste by pests and vectors; and
- prevent contact of the public.

Where controlled landfilling is not available, solutions should be found to minimize the transmission of infections and adverse impacts on the environment.

The WHO guide on safe management of wastes from health-care activities (21) should be reviewed for more details on waste treatment and disposal.

6.7 Further reading

Technical guidelines on the sound management of biomedical and healthcare wastes. Châtelaine: UNEP and Secretariat of the Basel Convention; 2003.

Report on the issues of the reprocessing of medical devices in the European Union. Brussels: European Commission; 2010.

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7. Special cases of medical devices decommissioning

In this section, we review types of medical device that require special care in decommissioning. They include sharps, devices containing mercury or radioactive sources, IVDs and laboratory devices, chemicals, implants, assistive devices and computer hardware and software. Location of these devices is subject to safety and security as well as access for disposal by others.

7.1 Sharps

Sharp or pointed objects and material that can cause injury and/or infection are classified as SUMDs. Examples of medical device sharps include syringes, needles, lancets, pipettes and glassware. Sharps with safety devices should be procured and used when available. The safety device should be activated immediately after use, and the whole object should be discarded to prevent the risk of sharps injuries. Hollow-bore needles used for blood sampling are considered particularly risky, as used needles contain blood. The decommissioning method for all sharps is disposal.

Disposal of these medical devices requires careful waste management. All sharps used on patients, in isolated wards and from laboratory waste confer a high risk of infection with communicable diseases and are categorized as infectious waste. Improper management of sharps can result in dissemination of communicable diseases.

The WHO department of HIV/AIDS published a guide to starting and managing needle and syringe programmes (38), which recommends that needles and syringes be organized from collection point to destruction. They should be stored in a labelled, puncture-proof, leak-tight container (e.g. Fig. 8) after use and separated from other waste. Only trained personnel should have access to storage of these wastes.

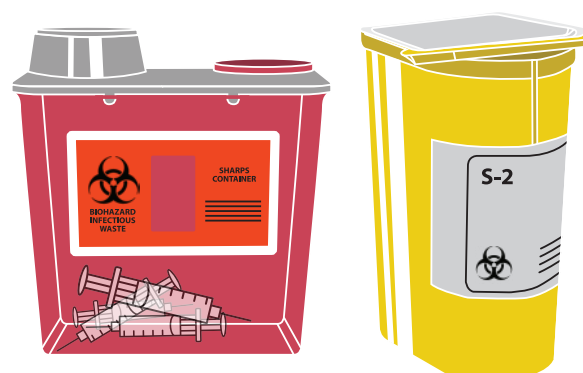


Fig. 8. Sharps disposal container

Source: (39)

Other practices are use of needle cutters, pullers or destroyers to remove needles from syringes (Fig. 9). Personnel should not manually bend or break needles. Leftover syringes should be placed in containers, and the containers with syringes can be transferred to a treatment facility or be destroyed before being released to the environment from an incinerator, if this service is available in the health care facility.

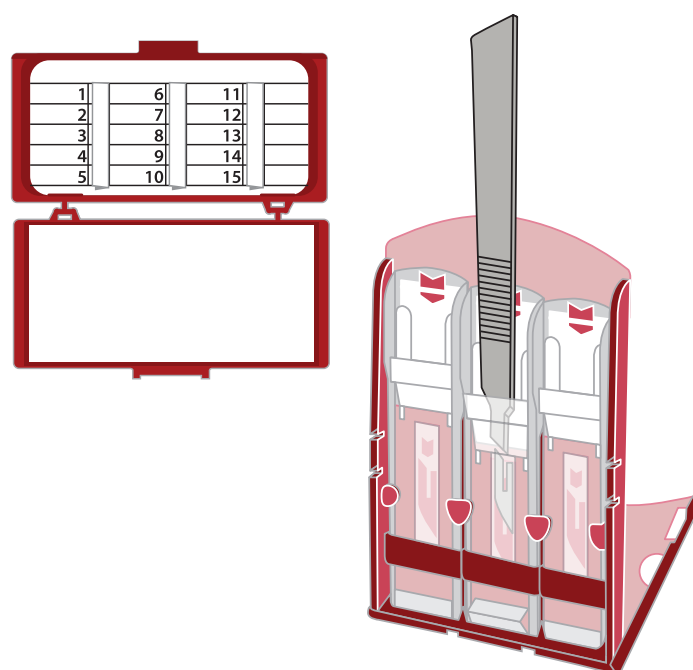


Fig. 9. Sharps disposal container and puller solutions

Source: Modified from Swann Morton products.

The following steps must be followed for treating sharps waste:

- Activate the safety device and/or separate needles from the syringes with a needle cutter or needle destroyer.
- Decontaminate and sterilize needles and syringes in an autoclave.
- Shred needles and syringes in an incinerator, if available.
- Bury sharps pieces in sharps pits or concrete vaults.
- Melt the plastics for recycling.

Complete guidelines can be found in the WHO publication safe management of wastes from health-care activities (21).

7.2 Devices containing mercury

Mercury is a heavy metal that does not occur naturally. It evaporates easily into the atmosphere, and people may be exposed by breathing air containing elemental mercury vapours. Inhaled elemental mercury vapour can have harmful effects on the nervous, digestive and immune systems and the lungs and kidneys. Once in the environment, mercury can be transformed by bacteria into methylmercury, which is toxic to the nervous system and a concern for developing fetuses. People are exposed to methylmercury through consumption of contaminated fish and shellfish. Mercury waste is therefore a great concern globally (40).

The Sixty-seventh World Health Assembly passed resolution WHA67.11 to protect public health from exposure to mercury and mercury compounds by implementation of the Minamata Convention on Mercury (41). The resolution encouraged 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.

The Minamata Convention established 2020 as the date for phasing out the manufacture, export or import of mercury-containing thermometers and sphygmomanometers, with possible country exemptions up to 2030. An open-ended exemption was also granted to products for research, calibration of instruments and use as a reference standard. Further information can be obtained from the 2015 WHO guidelines on phasing out mercury-containing thermometers and sphygmomanometers in health care (42).

Waste medical devices are one source of mercury in the atmosphere. Such devices include sphygmomanometers, thermometers, dental amalgams and batteries (Fig. 10). Care must be taken in all steps of handling devices that contain elemental mercury, from collecting and storing to transporting the devices and their disposal. Any mercury spill from broken devices should be removed immediately by proper procedures to avoid inhalation by health facility staff. Kits and guidelines for cleaning up spills of mercury in a proper, safe way are widely available, and responsible users and personnel should be trained. Mercury devices must not be placed in red (biohazard) medical waste containers or sharps containers but should be collected for hazardous waste disposal or



Fig. 10. Common medical devices that contain mercury

for designated recycling. An area dedicated to mercury waste within health care facilities should be determined before the waste is picked up for disposal. The next step is to send mercury waste to authorized facilities or to the original suppliers, if applicable. Another alternative is to send it to a disposal or storage site designated for hazardous industrial waste. For more information, see the WHO guidelines on safe management of wastes from health-care activities (21).

7.3 Radioactive sources

Radioactive sources are used in nuclear medicine, radiotherapy, medical research and diagnostic imaging, such as in cobalt therapy, single-proton emission computed tomography and positron emission tomography. A prime example of radioactive waste is material contaminated with radionuclides, which may be present in solid, liquid and gaseous forms. Short half-life radioactive materials can be classified as single-use devices, while long half-life radioactive materials are considered reusable devices and are usually used in radiotherapy, conditioned as a sealed source. The sealed source should be disinfected before reuse and stored in a container with a lead shield.

Decommissioning of radioactive sources usually ends with their disposal. The activity of radioactive materials should meet the clearance level before the waste is released from the health facility to be processed further. According to the International Atomic Energy Agency (43), the “clearance level” is the concentration and/or total activity at or below which a source of radiation may be released. When the activity of radioactive material has reached the clearance level, it can be disposed of by the usual methods. Methods for disposal of various types of radioactive materials used in medicine or medical services have been described by the International Atomic Energy Agency (44).

Until radioactive sources have met the clearance level, they should be stored within

health care facilities, with proper handling, in a lead container or in a lead-shielded room to prevent transmission to the environment. They should be placed in containers that prevent their dispersal before transport to a central facility to be disposed of or to the vendor. Plastic bags or other containers designated for radioactive material waste can be used. They should be clearly labelled, with information on the types and activity at a given date. WHO recommends lead boxes for storing radioactive waste, labelled with appropriate hazard symbols. A new radiation symbol was adopted by the United Nations in 2007, but the older symbol is still widely recognized and expected to remain in common use for many years (Fig. 11).



Old radiation symbol



New radiation symbol

Fig. 11. Radioactivity symbols

Source: (45, 46)

Radioactive sources in large devices, such as cobalt-60 used in teletherapy, should not be stored inside a hospital while being decommissioned. When such devices are designated for donation, trade-in, refurbishment or relocation, they should be transported carefully, especially when the radioactivity level is still high, and the responsible person should ensure that the device will not emit harmful radiation into the environment. Proper sealing, usually made of lead, should be used. Large radioactive sources might include housing; however, housing is not appropriate for transport or long storage of these devices. When radioactive sources are designated for disposal, they should be sent to an authorized institution or the manufacturer (43,47).

7.4 In vitro diagnostic devices

Laboratory devices include IVD medical devices, some of which are used at points of care. An IVD may be decommissioned because:

- It is a single-use IVD that must be disposed of after use, such as a rapid diagnostic test.
- It has unacceptable wear or damage or is unreliable.
- Its expiration date has been reached.
- It is under instruction for “field safety corrective action” issued by the manufacturer (e.g. recall to a manufacturer or destruction by the user under instruction of the manufacturer).
- The technology is obsolete.
- The necessary reagents or consumables are no longer commercially available.

Even after the sale of an IVD, the manufacturer is obliged to ensure that any risks related to its use throughout its life cycle (installation, use and disposal; Fig. 12) are managed in their risk management framework. Thus, the manufacturer is responsible for ensuring that their product can be disposed of safely. Each manufacturer shall establish and maintain continuous risk management throughout the product’s lifecycle, from conception to decommissioning, identify the hazards associated with an IVD, estimate and evaluate any risks and control the risks and evaluate the effectiveness of established controls. The programme shall include analysis, assessment, control and risk monitoring. Although the final responsibility for disposal of an IVD rests with the manufacturer, decommissioning of non-disposable IVDs, such as auxiliary equipment and analysers, might be affected by how the IVDs were procured. For example, in reagent rental or leasing, a clause should be present in the procurement contract to ensure that equipment to be decommissioned is decontaminated and removed safely by the manufacturer in a timely manner. When the device is procured as an outright purchase, the manufacturer should assist the user in decontaminating and disposing of the equipment in the most environmentally friendly way.

The safety considerations for disposal of an IVD depend on its category (see Table 3). “Biological safety” refers to measures to protect the user, patient and environment from any biological source of contamination. “Universal precautions” reflect an approach to infection control whereby



Fig. 12. Life cycle of IVD medical devices

Table 3. Safety considerations for decommissioning IVD devices

Category of IVD	Example	Safety consideration
Disposable, single-use	Reagents or test kits	Chemical and biological safety of the user, patient and the environment
Auxiliary equipment	Centrifuge, vortex, pipette, microplate washer and reader, incubator, microscope, heating plate	Biological and electrical safety of the user and the environment
Analysers	Dedicated equipment for clinical chemistry, haematology, serology, bacteriology, immunology, histopathology, nucleic acid testing	Electrical, chemical, biological safety of the user, patient and the environment

all human blood and certain other body fluids are treated as if they contained HIV, hepatitis C virus, hepatitis B virus and other bloodborne pathogens. Biological safety can be achieved by a variety of means, such as disinfection (with antimicrobial agents other than antibiotics or antiseptics), sterilization (in an autoclave) and use of other biocides. Practically, single-use rapid diagnostic tests can be autoclaved or incinerated before disposal. “Chemical safety”, “radiation safety” and “electrical safety” refer, respectively, to measures taken to protect users, patients and the environment from any harmful effects of exposure to chemicals, radiation and electrical sources due to malfunction, damage or inadequate design.

For more detailed information on IVD management, see WHO Guidance for procurement of in vitro diagnostics and related laboratory items and equipment (48). For devices containing radioactive or chemical material, see sections 7.3 and 7.5, respectively.

7.5 Chemicals

Chemical waste consists of discarded solid, liquid and gaseous chemicals generated during diagnosis with medical devices and during cleaning and disinfection. Chemical solvents are often used in pathology, laboratories and

engineering departments. Chemical waste poses significant risks and can be harmful to public health and the environment.

Chemicals used in laboratories in health care facilities can be categorized as consumables (Table 4). They must be handled responsibly and disposed of after use. Different types of chemical must not be mixed in order to avoid unnecessary or dangerous reactions. Pouring chemicals down the sewer or burying or encapsulating them are not acceptable unless recommended by the manufacturer, as these methods can harm public health and the environment if the instructions are not followed. Several options are available for disposing of chemical waste. When applicable, sending chemical waste back to the original supplier is the best option, and this service is sometimes included in purchasing agreements. Another option is to send them to an authorized institution that has the capability and expertise to dispose of hazardous chemicals. For more information on chemical waste management, refer to the WHO publication safe management of wastes from health-care activities (21).

Photographic fixing and developing solutions used in X-ray departments contain chemicals that are considered hazardous wastes. Fixer usually contains 5–10% hydroquinone, 15% potassium hydroxide and < 1% silver; the developer contains approximately 45% glutaraldehyde.

Table 4. Chemical waste from health care activities

Chemical waste	Examples
Halogenated solvents	Chloroform, methylene chloride, perchloroethylene, refrigerants, trichloroethylene
Non-halogenated solvents	Acetone, acetonitrile, ethanol, ethyl acetate, formaldehyde, isopropanol, methanol, toluene, xylenes
Halogenated disinfectants	Calcium hypochlorite, chlorine dioxide, iodine solutions, iodophors, sodium, dichloroisocyanurate, sodium hypochlorite
Aldehydes	Formaldehyde, glutaraldehydes, ortho-phthalaldehyde
Alcohols	Ethanol, isopropanol, phenols
Other disinfectants	Hydrogen peroxide, peracetic acid, quaternary amines
Metals	Arsenic, cadmium, chromium, lead, mercury, silver
Acids	Acetic, chromic, hydrochloric, nitric, sulfuric
Bases	Ammonium hydroxide, potassium hydroxide, sodium hydroxide
Oxidizers	Bleach, hydrogen peroxide, potassium dichromate, potassium permanganate
Reducers	Sodium bisulfite, sodium sulfite
Miscellaneous	Anaesthetic gases, asbestos, ethylene oxide, herbicides, paints, pesticides, waste oils

Source: (21)

Acetic acid is used in both stop baths and fixer solutions. Spent fixing and developing baths should be mixed carefully according to the manufacturer’s specifications.

The steps in disposing of fixing and developing baths should be as follows.

- Personnel who neutralize and dispose of chemical waste should be trained in safe removal procedures; personal protective equipment and safety equipment should be provided.
- X-ray chemical waste should be collected separately from other chemical waste because of the value of the silver content, which can be recovered by ion exchange, electrolytic recovery or filtration.
- Neutralized waste solution should be properly labelled in a secondary container and stored for ≤ 1 day.
- Wastes should be diluted 1:2 with water and poured slowly into a sewer. Chemicals should not be mixed.
- All chemicals should be clearly labelled, and safety data sheets should be available and

accessible in the case of accidental exposure or spill. Containers and consumables should be labelled to ensure safety in the workplace.

- A service log is recommended to track the dates, types of service performed, cartridge changes and volume of waste disposed of. Cartridges should be marked with the date of installation.

Waste from conventional X-ray machines for which a dark room is still used to process films must be handled separately.

7.6 Implants

Implants are considered single-use devices and their end status should be “dispose”, as recommended in section 5. Reuse of implants such as pacemakers has, however, been increasing, and international studies of this practice are described in this section. Reuse of implants is nevertheless not recommended, as this is not their intended use.

Pacemakers (Fig. 13) are classified as SUMDs; however, there is high demand in low- and middle-income countries for affordable implants, and reuse of pacemakers has been documented in countries where access to new medical devices is difficult. The US Food and Drug Administration guidance on pacemaker reuse (49) states that “there is a serious question whether pacemakers can be properly re-sterilized following initial implantation due to the possibility of body fluids entering the terminal leads of the pacemaker”. While a number of studies indicated no increased rate of infection or mortality, there are no regulations on reprocessing and reuse of pacemakers.

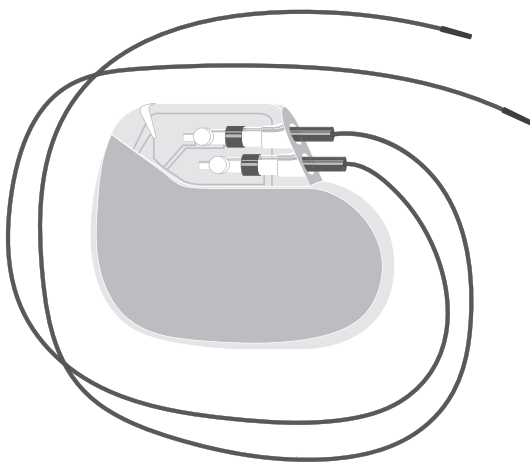


Fig. 13. Pacemaker

Source: (50)

Although reuse is against the intended use of the device and is not recommended, considerations to be made when they are reused are:

- the decision of the original owner at the end of life,
- the quality of the device,
- the absence of regulation and validated cleaning and sterilization procedures and
- the liability of reproprocessors to respect the regulations of the original manufacturer.

The last consideration refers to the liability associated with reprocessing SUMDs, as the obligation of the original SUMD manufacturer for regulation is transferred to the reproprocessor, as discussed in section 5.2.

It is recommended that the original owner of the pacemaker provide a “living will” with regard to his or her pacemaker or defibrillator at the time of implantation, authorizing the recovery, donation or decommissioning of the device after upgrading or death. Donated pacemakers should have more than 70–80% of their original battery life (51,52). The quality of the device’s safety features, performance and battery life should be tested and patient information removed. Although there are no validated instructions for cleaning and sterilizing SUMDs for reuse, some studies have demonstrated that reuse of properly refurbished pacemakers is feasible and safe. In these studies, the methods included professional cleaning with a brush, detergent and water, packaging of the device and sterilization with ethylene oxide (51).

7.7 Computer software and hardware

In the absence of globally standardized procedures for decommissioning computer software and hardware, WHO recommends that all data and patient information be removed from devices before they reach their end status. A biomedical or clinical engineer, if available, or the person responsible for use of the medical equipment should safely store and delete patient information from the software and/or the hardware of equipment such as intensive care monitors, laboratory information systems, radiology information systems and any other device that holds patient information.

“Media sanitization” is a process that makes access to the data on media impossible. Concern about information privacy and security in information disposal and media sanitization not about the media but about the recorded information. Media containing sensitive information, patient data and registered software include magnetic storage, optical storage, solid state storage and hard copy storage. Methods for sanitizing a device to dispose of the media include degaussing, disintegration, incineration and shredding. Some manufacturers will take back computer software or hardware to recycle and dispose of it properly. When this option is not

available, a biomedical engineering department might be able to reuse computer software or hardware parts. If reuse is not possible, computer waste should be sent to authorized facilities capable of depollution and dismantling waste of electronic and electrical equipment according to European treatment standard EN 50625. If there is no authorized facility in the country, computer waste must be handled by operators who are aware of and trained in the health and environmental toxicological impacts of e-waste. Another alternative is to send such waste to a disposal or storage site designated for hazardous waste; however, the patient information and other confidential information must still be erased or destroyed.

7.8 Electronic waste

In countries with waste management policies, e-waste is often collected by individuals or companies for metal recycling, plastic recycling, further specialized e-waste recycling, and sometimes exportation. Exportation may also occur to developing countries, as donations, where it is often informally recycled. E-waste contains potentially hazardous substances that may be released directly and others that may be formed during the recycling process, especially if this occurs in the “informal” sector where modern industrial processes are not used and where worker protection may be inadequate. Because of their little hands, children are often involved in these processes, being exposed to high quantities of toxic chemicals, such as lead, mercury and cadmium into the environment. Because of the high levels of environmental, food, and water contamination, residents living within a specific distance of e-waste recycling areas are also at risk of environmental exposure. Only about 20 % of the approx. 50 million metric tons generated every year e-waste is formally recycled. Countries need support to recognize the challenge e-waste poses to their population-s health and develop e-waste policies and reduce, recycle and dispose of e-waste sustainability.

7.9 Further reading

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8. Concluding remarks

Selecting and commissioning medical devices receives much attention, whereas decommissioning and disinvestment are considered less interesting and are not addressed or consideration is postponed due to lack of information on how to proceed. Devices that should be decommissioned can harm patients or health care workers and should therefore receive proper attention. To bridge the gap in knowledge about decommissioning medical devices, WHO is providing practical guidelines as part of its Medical devices technical series to refine policies and procedures.

Proper medical device decommissioning can improve patient safety and resource management and yield economic benefits. Understanding the life cycle of these devices and determining their best end status can extend the life of the device and ensure safe, appropriate devices for relocation, donation and reuse or safe disposal. The dangers associated with unsupervised, inappropriate disposal of medical devices are described in this document. A major concern is that donation of faulty medical equipment to low-income settings causes more harm than good. Furthermore, unnecessary filling of landfills with health care waste increases the risk for infection and other harm to the public and environmental health.

New devices are coming onto the market and into health care systems every day, as new materials and new medical technologies are developed. It is therefore important to know how to discard them safely and to ensure that reuse is approved or authorized by competent authorities. The priority should always be the well-being of patients and health care workers, assured by good-quality medical technology that can achieve the intended purpose effectively and is used safely and appropriately. Any devices that cannot deliver these services should be considered for decommissioning or disinvestment.

This guide do not specifically assign the types of spaces, environment, space organisation, processes or standard operating procedure (SOP) per se. Operation and provision of spaces and facilities will rely on the local climatic condition, technology, security, safety and available guidelines to ensure no harm to the patient, the health workers, other users and society at large (in landfill, waste, non-registered health centres) in the process of decommissioning of medical devices.

This guidance document will be updated as more information becomes available and as procedures for decommissioning specific types of medical devices are considered to avoid harm to patients and health care workers.

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10. Links to organizations

WHO

WHO Medical device technical series: http://www.who.int/medical_devices/management_use

WHO Diagnostic imaging: http://www.who.int/diagnostic_imaging

In vitro diagnostics and laboratory technology: http://www.who.int/diagnostics_laboratory

Medical devices: http://www.who.int/medical_devices

Raising awareness on e-waste and children's health: <https://www.who.int/activities/raising-awareness-on-e-waste-and-children-s-health>

Other United Nations bodies

International Atomic Energy Agency (IAEA): <https://www.iaea.org/>

United Nations Environment Programme (UNEP): <http://www.unep.ch/>

United Nations Population Fund (UNFPA): <http://www.unfpa.org/>

Basel Convention: <http://www.basel.int/>

Nongovernmental organizations

Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (DITTA): <http://globalditta.org/>

Global Medical Technology Alliance (GMTA): <http://www.globalmedicaltechnologyalliance.org/>

Health Technology Assessment International: <https://htai.org/>

HUMATEM: <http://www.humatem.org>

International Federation for Medical and Biological Engineering (IFMBE) <http://ifmbe.org/>

International Federation of Biomedical Laboratory Science (IFBLS): <http://www.ifbls.org/>

International Federation of Hospital Engineering (IFHE): <http://www.ifhe.info/>

International Society of Radiographers and Radiation Technologists (ISRRT): <https://www.isrrt.org/history-isrrt>

International Society of Radiology (ISR): <http://www.isradiology.org/>

Tropical Health and Education Trust (THET): <https://www.thet.org/>

Union of International Architect, Public Health Group: <https://www.uia-phg.org/>







World Association of Societies of Pathology and Laboratory Medicine (WASPALM): <http://www.waspalm.org/>

World Federation for Ultrasound in Medicine and Biology (WFUMB): <http://www.wfumb.org/>

Annex 1. Labelling and colour-coding of health care waste

Various colour coding and marking systems are used according to national or regional guidelines. Consistent, clear marking of wastes is of the upmost importance.

Table A1. WHO-recommended scheme for segregating waste

Type of waste	Colour of container or bag	Type of container
Highly infectious	Yellow Marked "HIGHLY INFECTIOUS"	 Strong, leak-proof plastic bag or autoclave-compatible container
Other infectious and pathological	Yellow	 Plastic bag or container
Sharps	Yellow Marked "SHARPS"	 Puncture-proof container
Chemical and pharmaceutical	Brown	 Plastic bag or container
Radioactive	Marked with the radioactive symbol	 Lead box
General health care	Black	 Plastic bag

Source: From Chartier Y, Emmanuel J, Pieper U, Prüss A, Rushbrook P, Stringer R, et al., editors. Safe management of wastes from health-care activities. Second edition. Geneva: World Health Organization; 2014 (https://apps.who.int/iris/bitstream/handle/10665/85349/9789241548564_eng.pdf?sequence=1, accessed October 2019).



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