

Decommissioning Medical Devices

WHO Medical Device Technical Series







Decommissioning of Medical Devices

WHO Medical Device Technical Series



Decommissioning medical devices

(WHO medical device technical series)

ISBN 978-92-4-151704-1

© World Health Organization 2019

 $Some \ rights \ reserved. \ This \ work \ is \ available \ under \ the \ Creative \ Commons \ Attribution-NonCommercial-Share Alike \ 3.0 \ IGO$

licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work,

you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English

edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules

of the World Intellectual Property Organization.

Suggested citation. Decommissioning medical devices. Geneva: World Health Organization; 2019 (WHO medical device

technical series). Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for

commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission

from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work

rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply

the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps

represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or

recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted,

the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the

published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design & layout: L'IV Com Sàrl, Switzerland

Printed in Switzerland

Contents

Ack	nowle	edgements	. V
Glos	ssary		vi
Pre	face.		ix
1.	Intro	duction and purpose	. 1
2.		cal devices	
	2.1	Life cycle	
	2.2	Further reading	
3.	Deco	mmissioning.	. 4
	3.1	Implementation	
	3.2	Risk auditing and cost assessment	. 5
	3.3	Personnel	. 6
	3.4	Infrastructure	. 6
	3.5	Decontamination of devices	. 6
	3.6	Removal of patient data	. 8
	3.7	Waste management	. 8
	3.8	Inventory system and decommissioning report	. 8
	3.9	Further reading	. 8
4.	Disin	vestment	10
	4.1	Stages of disinvestment	10
	4.2	Identification	
	4.3	Context-specific prioritization	
	4.4	Implementation	
	4.5	Impact analysis	
	4.6	Summary	
	4.7	Further reading	
5.		le-use medical devices	
	5.1	Disposal	
	5.2		13
	5.3	Further reading	15 16
6.	Reusable medical devices		
	6.1	Reassignment	
	6.2	Refurbishing	
	6.3	Donation	
	6.4		
	6.5 6.6	Trade-in	
	6.7	Further reading	
	0.7	- r urunor roduing	~~

7. •	Special cases of medical devices decommissioning	23
	7.1 Sharps	23
	7.2 Devices containing mercury	24
	7.3 Radioactive sources	25
	7.4 In vitro diagnostic devices	26
	7.5 Chemicals	27
	7.6 Implants	
	7.7 Computer software and hardware	
	Fig. 13. Pacemaker	
	7.8 Electronic waste	
	7.9 Further reading	
8.	Concluding remarks	32
9.	References	33
10.	Links to organizations.	36
Anne	ex 1. Labelling and colour-coding of health care waste	37
Figu	res and tables	
Fig. 1	1. Medical device life cycle	. 2
	2. Decommissioning medical devices	
Fig. 3	3. Decontamination life cycle	. 7
Fig. 4	4. Stages of disinvestment	10
Fig. 5	5. Harmonized symbol for single-use products	13
Fig. 6	6. Five-step refurbishing process	17
	7. Soliciting and offering donations of medical equipment	
_	8. Sharps disposal container	
_	9. Sharps disposal container and puller solutions	
_	10. Common medical devices that contain mercury	
	11. Radioactivity symbols	
Fig	12. Life cycle of IVD medical devices	26
	e 1. Examples of medical devices by risk class.	
	e 2. Health care waste categories	
	e 3. Safety considerations for decommissioning IVD devices	
	e 4. Chemical waste from health care activities	
Iable	e A1. WHO-recommended scheme for segregating waste.	3 /

Acknowledgements

World Health Organization

Medical Devices Unit, Department of Essential Medicines and Health Products

- Adriana Velazquez-Berumen, Senior Advisor Medical Devices, general coordination of the project
- Anita Sands, Regulation of Medicines and Other Health Technologies
- Magdalena Plotczyk (May–September 2019) and Valeria Montant (September–December 2019), interns, who compiled and reviewed the last version of the document and incorporated the comments of experts and WHO staff.
- Ruth Christiani (June–August 2014), Sara Al-akbari (June–August 2015), Jennette Leung (December 2015–March 2016) and Joshua Daniel (December 2018–May 2019), interns, who wrote the first draft and compiled documents.

Other WHO departments

- Carolyn Vickers, Team Leader, Chemical Safety
- María del Rosario Pérez, Technical Officer, Radiation Protection
- Oumar Sheick Coulibaly, Technical Officer, Health Technologies and Innovations, AFRO
- Marie Noel Brune, Technical Officer, Public Health Environment and Social Determinants of Health

External contributors

- Ajai Basil, National Health Systems resource center (NHRSC)
- Benoît-Pierre Ligot, Médecins Sans Frontières, France and Humatem France
- Cathy Blanc-Gonnet, Humatem, France
- Dinsie Williams, biomedical engineering consultant, Canada and Sierra Leone
- Eunice Lourenço, Portugal and Regulatory Consultant at WHO, Switzerland
- Hugues Gaertner, Médecins Sans Frontières, Spain and Humatem France
- Iñaki Gutierrez Ibarluzea, Director, Managerial and Organizational Innovation, Basque Foundation for Health innovation and Research, Spain
- Dr. Jitendar Sharma, Senior Fellow, Niti Aayog, India and Consultant at WHO, Switzerland
- Julie Polisena, co-opted member of the International Federation of Medical and Biological Engineering, Canada
- Mohammad Ameel, National Health Systems resource center (NHRSC)
- Tobey Clark, WHO Collaborating Centre for Health Technology Management, USA
- Zheng Kun, Children's Hospital of Zhejiang University School of Medicine, China

Peer reviewers

- · Ali Al Dalaan, Saudi Food and Drug Authority, medical device sector
- Azzam Al Othman, Saudi Food and Drug Authority, medical device sector
- Karin Imoberdorf, Public Health Group, International Union of Architects
- Marie Nora Roald, International Federation of Biomedical Laboratory Science
- Martin Raab, Swiss Centre for International Health, Swiss Tropical and Public Health Institute
- Norwina Mohd Nawawi, Public Health Group, International Union of Architects
- Roberto Ayala, CENETEC, WHO Collaborating Center, Mexico
- Stewart Whitley, Director, Professional Practice, International Society of Radiographers and Radiologic Technologists
- Zhipeng Lu, Public Health Group, International Union of Architects

Declarations of interests

Declarations of interests were collected from all contributors and peer reviewers involved in preparing the document. No conflict of interests were identified regarding the topic of this book.

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

预览已结束,完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5_25380

