# MEDICAL EQUIPMENT PROACTIVE ALLIANCE FOR SUSTAINABLE HEALTHCARE

# SUSTAINABILITY CRITERIA FOR PURCHASING MEDICAL IMAGING DEVICES

LIST OF RELEVANT CRITERIA

MAY 2024

Medical Equipment Proactive Alliance for Sustainable Healthcare

- 🥱 COCIR (www.cocir.org)
- HEALTHTRUST PERFORMANCE GROUP (www.healthtrustpg.com)
- VIZIENT INC (www.vizientinc.com)

In consultation with

- GLOBAL ELECTRONICS COUNCIL® (www.globalelectronicscouncil.org)
- KAISER PERMANENTE (https://thrive.kaiserpermanente.org/)

#### INTRODUCTION

This document provides a set of relevant criteria which may be useful for sustainable/green procurement of medical imaging devices. Based on the "<u>State of Sustainability Research for Medical Imaging Devices</u>", prepared by the Global Electronics Council® in 2022 for the "Medical Devices Proactive Alliance for Sustainable Healthcare", the criteria aim to reduce the climate, environmental and social impacts of medical imaging devices supplied to the healthcare sector. The criteria were developed through a collaborative effort between industry and group purchasing organisations (GPOs). This

collaboration ensured that the criteria were science-based and relevant to the goal of reducing the sustainability footprint of medical imaging devices.

The purpose of the criteria is to:

- Assist those responsible for public sector tenders, e.g. category managers, public procurement officers or procurement consultants, to define specific criteria relevant to the specific procurement;
- Provide a common understanding and guidance to relevant and responsible stakeholders on sustainable/green procurement.

The criteria are divided into four key areas, in line with best practice in sustainability, and can be related to both the sustainability performance of the product:

- ✓ Climate change mitigation
- ✓ Sustainable use of resources
- 🥏 Use of chemicals of concern
- 🥏 Social impacts

While many other criteria can be identified and may be routinely used in other product categories, the criteria in this list are relevant to the medical imaging device sector. They have also been assessed to ensure that they do not compromise patient safety requirements, product approval procedures or safety standards.

Due to the specifics of the sector, criteria used for other product groups may not be applicable. We would recommend using the criteria and not going beyond them without proper evaluation to avoid creating unnecessary bureaucracy for limited benefit.

The criteria are recommendations and are divided into three levels:

- Basic criteria are designed to allow easy application in sustainable/green public procurement. Fulfilment of all the basic criteria is considered to be the minimum requirement for a company or product to be considered to be contributing to the sustainability of healthcare.
- **Intermediate criteria** are designed to achieve higher levels of sustainability performance.
- **Advanced criteria** are designed for excellent sustainability performance, being at the forefront of the industry.

#### NOTE 1: Some criteria should not be used to compare products

It is not the intention of criteria that require the disclosure of a value, such as energy consumption, to allow comparison of products. The intention is to assess the ability of companies to use tools and appropriate design choices and to measure performance, which is a prerequisite for continuous improvement.

#### NOTE 2: Trade-off

The criteria presented in this document are generic to companies and medical imaging devices. Therefore, feasibility must be assessed in the pre-tender process before any criteria are applied. If the criteria compromise safety, regulatory or standard requirements for a specific product, they should not be applied.

In developing the criteria, trade-offs have been considered as much as possible to avoid companies or buyers having to resolve trade-offs themselves with sub-optimal compromises. For example, reducing the weight of a medical imaging device may result in increased vibration during operation or require higher impact materials.

#### DISCLAIMER

The authors assume no responsibility or liability for any errors or omissions in the content of this guidance. The guidance is intended solely for general guidance, and is not intended to constitute legal, tax, accounting or other professional advice of any kind.

#### LIST OF ABBREVIATIONS

AIHA: American Industrial Hygiene Association

ANSI: American National Standards Institute

**CDP:** a not-for-profit organisation that operates the global disclosure system for investors, companies, cities, states and regions to manage their environmental impacts.

EMS: Environmental management system

FMD: Full material declaration

FSC: Forest Stewardship Council.

IEC: International Electrotechnical Commission

ISO: International Organization for Standardization

ISSB: International Sustainability Standards Board

LCA: Life Cycle Assessment

**OHSAS:** Occupational Health and Safety Assessment Series

**PEFC:** Program for the Endorsement of Forest Certification

R2: Responsible Recycling Standard for Electronics Recyclers

**RBA:** Responsible Business Alliance Foundation

RoHS: Directive 65/2011/EC on the restriction of use of certain hazardous substances

SVHC: Substances of very high concern

TCFD: Task Force on Climate-related Financial Disclosures

WEEE: Waste electric and electronic equipment

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# **CRITERIA LIBRARY**

**BLUE:** CRITERIA RELATED TO **PROCESSES** AND **PROCEDURES** (company level) **GREEN:** CRITERIA RELATED TO **PRODUCT PERFORMANCES** (product level)

# LIFE CYCLE ASSESSMENT

# **1. LIFE CYCLE ASSESSMENT: BASIC**

The tenderer shall use life cycle assessment tools for representative or individual models in order to identify design options to reduce the environmental impact of medical devices or alternative eco-design processes.

- 🥏 The LCA includes as a minimum the bill of materials and energy consumption;
- ISO/IEC62430 lists many additional tools that can be used with similar results to LCA, especially for mature technologies such as medical devices.

#### 1.1. LIFE CYCLE ASSESSMENT: ADVANCED

The tenderer shall declare the carbon footprint / LCA results for representative or individual models covered by the tender, including information on the calculation and methodologies/tools used.

# **CLIMATE CHANGE MITIGATION**

# 2. ENERGY MANAGEMENT: BASIC

The tenderer shall put in place a management system to address energy efficiency at least for the company's sites and operations, including logistics.

#### 2.1. ENERGY MANAGEMENT: INTERMEDIATE

The tenderer shall implement a management system to address the energy efficiency of the company's sites and operations and the design of its products.

# 2.2. ENERGY MANAGEMENT: ADVANCED

The tenderer shall implement a management system to address the energy efficiency of the company's sites and operations, its product design and its supply chain.

# 3. CARBON NEUTRALITY AND RENEWABLE ENERGY: BASIC

The tenderer has a policy to become carbon neutral throughout its operations and production, with clear targets and milestones. The tenderer shall provide information on how the targets will be achieved.

#### 3.1. CARBON NEUTRALITY AND RENEWABLE ENERGY: INTERMEDIATE

The tenderer shall report publicly on the use of renewable electrical energy in its operations and production.

#### 3.2. CARBON NEUTRALITY REPORTING: INTERMEDIATE

Reporting will be in accordance with standard reporting frameworks (CDP, ISSB/TCFD, etc.).



#### 3.3. CARBON NEUTRALITY AND RENEWABLE ENERGY: ADVANCED

The tenderer is carbon neutral in its operations and in its production.

#### 3.4. CARBON NEUTRALITY AND RENEWABLE ENERGY: ADVANCED

The tenderer shall provide the product level measurement of the embodied carbon, with information on the boundaries/ methodologies used.

#### 3.5. CARBON NEUTRALITY: ADVANCED

Targets that are aligned with international standards such as the United Nations' Science Based Targets Initiative (SBTi).

#### 4. COMMUNICATION OF ENERGY CONSUMPTION: BASIC

The tenderer shall provide the measured energy consumption of the medical imaging devices covered by the tender according to the COCIR methodology<sup>1</sup> and the power consumption per mode.

#### 4.1. COMMUNICATION OF ENERGY CONSUMPTION: ADVANCED

The tenderer shall provide a declaration of the energy consumption of the medical imaging devices covered by the tender according to the scenario defined in the tender (number of examinations per day and type of examinations).

## 5. SAVING ENERGY MODES: BASIC

The product is equipped with energy saving options, such as switching to low power modes.

#### 5.1. SAVING ENERGY MODES: ADVANCED

The product is equipped with user-configurable energy management options.

#### 5.2. SAVING ENERGY MODES: ADVANCED

The tenderer shall provide assistance in tracking and optimising the energy consumption of the medical device covered by the tender throughout its life cycle.

## 6. INSTRUCTIONS FOR SUSTAINABLE USE: BASIC

The tenderer shall provide instructions on how to maximise the environmental performance of the specific medical device in written form, either as a specific part of the instruction manual, or in digital form accessible via the manufacturer's website, or on a CD, or in paper form on the packaging or documentation accompanying the product. The instructions shall be made available with the equipment. The documentation shall, as a minimum requirement and without compromising the clinical performance of the device, include instructions for users on how to use the device in order to minimise its environmental impact during installation, use, maintenance and recycling/disposal, including instructions on how to optimise the consumption of energy, water, consumables/parts and, where appropriate, emissions.

#### 7. TRAINING FOR ENERGY EFFICIENCY OPTIMISATION: INTERMEDIATE

The tenderer shall provide end-user training that includes elements on setting and fine-tuning the energy parameters of the equipment (e.g. standby mode) to optimise electricity use. Training may be integrated into the clinical and technical training provided by the tenderer.



# SUSTAINABLE USE OF RESOURCES

# 8. REUSE: ADVANCED

The tenderer shall declare the total plastic content and the percentage of virgin plastic, recycled plastic and bio-based plastic.

## 8.1. REUSE: ADVANCED

The tenderer shall declare the recycled metal content of the medical device as well as the concentrations of recycled metal in its main components.

## 9. REFURBISHMENT: INTERMEDIATE

The tenderer shall implement a refurbishment/remanufacturing business that includes:

- ✓ A take-back system for used devices and parts from customers.
- Reverse logistics.
- ✓ Refurbishment in accordance with the IEC63077 standard.
- Reselling with a warranty comparable to a new device.

# **10. CIRCULAR ECONOMY: ADVANCED**

The tenderer shall have a program for the re-use of material from the products covered by the tender, which tracks and documents:

- Criteria 10.1: total quantities reused in tonnes.
- Criteria 10.2: quantities of equipment, components and materials reused.

# 11. PACKAGING: REDUCTION OF PACKAGING AND PACKAGING WASTE: BASIC

The tenderer shall have a strategy or plan to reduce the amount of packaging material or increase its sustainability. The tenderer shall track the total amount of materials used per year.

# 12. PACKAGING COMPOSITION: BASIC

The tenderer shall declare the composition of the packaging for the medical device, the rate of recyclability and the content of recycled material.

#### 12.1. PACKAGING COMPOSITION: INTERMEDIATE

The tenderer declares that the packaging is free from expanded / extruded polystyrene (EPS).

#### 12.2. PACKAGING COMPOSITION: INTERMEDIATE

The tenderer declares that the packaging is PVC-free.

# **13. SUSTAINABLE FORESTRY: INTERMEDIATE**

If the tertiary and/or secondary packaging is fibre-based, the tenderer shall disclose to customers the ratio of FSC/PEFC certified sustainable fibres to non-FSC/PEFC certified sustainable fibres (the ratio should be at least 50%).

#### 13.1. SUSTAINABLE FORESTRY: ADVANCED

If the tertiary and/or secondary packaging is fibre-based, the tenderer shall disclose to customers the ratio of FSC/PEFC certified sustainable fibres (or otherwise sustainably sourced wood) to non-FSC/PEFC certified sustainable fibres (the ratio should be at least 95%).



#### 13.2. SUSTAINABLE FORESTRY: ADVANCED

If packaging and/or manual/leaflet is fibre-based: At least 90% FSC/PEFC certified (or otherwise sustainably sourced wood) or recycled fibre.

## 14. WASTE & PACKAGING (BASED ON THE KAISER PERMANENTE EPP STANDARD<sup>2</sup>): BASIC

The product must meet at least two (2) of the following criteria.

- The product does not generate hazardous waste The product is not regulated as a hazardous waste when used as intended and discarded.

- ↗ Primary packaging contains more than 10% post-consumer recycled content.
- Secondary packaging contains more than 30% post-consumer recycled content, excluding fibre-based materials such as wood.
- Packaging is recyclable.

## **15. END OF LIFE: BASIC**

The tenderer shall ensure that the treatment of WEEE generated during production, repair and refurbishment, as well as the treatment of WEEE returned to the company, is carried out by facilities that meet the requirements of the following standards:

- European standards EN 50625 and EN 50614, which cover the process of collection, transport and treatment of WEEE (or US equivalent).
- ↗ The Responsible Recycling (R2) standard for electronics recyclers.
- ↗ The e-Stewards standard for the responsible recycling and reuse of electronic equipment.

# **16. RECYCLING PASSPORTS: BASIC**

The tenderer shall demonstrate that it will make recycling instructions available to recyclers on request, including information on safe dismantling, removal of hazardous parts or other substances that may impede recycling.

- The information shall be available on request in one or more of the following formats:
  - easy-to-use formatting on the web;
  - 🥏 downloadable PDFs for offline viewing; or
  - 🥏 machine-readable file format: either HTML, XML or IEEE 1874, the IEEE standard for documentation.



# CHEMICALS OF CONCERN

# **17. CHEMICAL MANAGEMENT SYSTEM: BASIC**

The tenderer shall provide documentation demonstrating that a chemical management system is in place with dedicated resources, expertise, documented routines and informatics tools to ensure that the company is aware of the presence of regulated or declarable substances and/or additional SoC in the medical devices covered by the tender. This may include:

- A list of the regulated/declarable/additional substances that are continuously tracked throughout the supply chain and may be present in the product (The tenderer shall record the presence of IEC 62474 declarable substance groups and declarable substances in the product at or above the reporting thresholds identified in the IEC 62474 database. The record shall include all declarable substance groups and declarable substances identified as Criteria 1, 2 and 3 in the IEC 62474 database.)
- That information on the presence of listed substances, including new additions to the list, is requested from suppliers on a regular basis (at least every 6 months).
- A systematic collection and archiving of information received from the supply chain on the products covered by the tender, i.e. record keeping and monitoring procedures (e.g. regular review of documentation on SoC content in the product and spot checks of chemical content such as laboratory analysis reports) to evaluate collected information for inconsistencies.
- A policy to encourage suppliers to share information on Substances of concern content.

## 17.1. CHEMICAL MANAGEMENT SYSTEM: ADVANCED

The informatics tool can also accept Full Material Declarations and the Company has a policy of encouraging suppliers to provide FMDs.

# **18. EU ROHS DIRECTIVE COMPLIANCE: BASIC**

The product shall comply with the restriction requirements of the European Union RoHS Directive and its amendments in force at the time of the declaration. All exemptions from the substance restrictions as defined in the Directive apply.

# **19. EU REACH REGULATION COMPLIANCE: BASIC**

The tenderer shall disclose the content of SVHC substances in accordance with the requirements of Article 33 of the EU REACH Regulation in force at the time of the tender.

# 20. PVC CONTENT (BASED ON THE KAISER PERMANENTE EPP STANDARD): INTERMEDIATE

Polyvinyl chloride (PVC) - the product contains less than 1,000 ppm (0.1%) of polyvinyl chloride. This criterion does not apply to electronic cords, cables and connectors.

# 21. BFR CONTENT (BASED ON THE KAISER PERMANENTE EPP STANDARD): ADVANCED

Halogenated flame retardants - All homogeneous materials contain less than 1,000 ppm (0.1%) of brominated and chlorinated compounds. For electronic products, this criterion only applies to the product casing as defined by TCO\*

\* TCO definition of "housing" "Product housing is considered to be the external enclosure or casing that protects the internal parts of a product. This includes a product stand and external power supplies."



# 22. SVHC CONTENT (BASED ON THE KAISER PERMANENTE EPP STANDARD): INTERMEDIATE

All homogeneous materials contain less than 1,000 ppm (0.1%) of SVHCs not subject to EU Authorisation (REACH Annex XIV)<sup>4</sup>. For electronic products, this criterion only applies to the product casing as defined by TCO\*

\* TCO definition of "housing" "Product housing is considered to be the external enclosure or casing that protects the internal parts of a product. This includes a product stand and external power supplies."

## 23. SVHC CONTENT (BASED ON THE KAISER PERMANENTE EPP STANDARD): ADVANCED

All homogeneous materials contain less than 1,000 ppm (0.1%) of SVHCs subject to EU Authorisation (REACH Annex XIV)<sup>5</sup>. For electronic products, this criterion only applies to the product casing as defined by TCO\*

\* TCO definition of "housing" "Product housing is considered to be the external enclosure or casing that protects the internal parts of a product. This includes a product stand and external power supplies."

# 24. BATTERIES: BASIC

The tenderer shall declare that the batteries in the product comply with the substance restriction requirements and any other requirements of Regulation (EU) 2023/1542 of 12 July 2023 and any subsequent amendments in force at the time the batteries are manufactured (including transition periods for implementation).

#### 24.1. BATTERIES: INTERMEDIATE

The tenderer shall provide a list of the batteries contained in or sold with the product, including their chemistry (e.g. lithium-ion, nickel-metal hydride, etc.)

#### 25. SUBSTANCE HAZARD ASSESSMENT: ADVANCED

The manufacturer shall demonstrate that for substances performing the following functions in housing/casings as defined by TCO,

1) flame retardants > 0.1% w/w in homogeneous materials of plastic parts > 0.5 g

2) plasticisers > 0.1% w/w in homogeneous materials of plastic parts > 0.5 g

a substance hazard assessment has been carried out using tools such as Greenscreen, Scivera GHS+, Cradle to Cradle, ChemForward Hazard Bands or a comparative assessment tool.

<sup>3</sup> https://webstore.iec.ch/publication/29857
4 https://www.echa.europa.eu/authorisation-list

<sup>5</sup> https://www.echa.europa.eu/authorisation-list



# **CORPORATE ESG PERFORMANCE**

# 26. ENVIRONMENTAL MANAGEMENT SYSTEM: BASIC

The tenderer shall have a formal, self-declared EMS for those parts of the company that have significant responsibility for the design and manufacture of the products covered by the tender. The EMS shall meet the requirements of ISO 14001. Certification to either ISO 14001 or EMAS (European Union Eco-Management and Audit Scheme) fulfils this requirement.

# 27. COMMITMENT TO CONTINUOUS IMPROVEMENT: ADVANCED

The tenderer shall have a commitment to continuous improvement in environmental and social responsibility, including labour and human rights, evidenced by a written public commitment from a senior company official. The commitment shall cover both its operations and its suppliers.

# 28. OCCUPATIONAL HEALTH AND SAFETY: BASIC

The tenderer declares to comply with occupational health and safety performance as set out in

- 对 ISO 45001 Occupational Health and Safety Management Systems,
- ANSI/AIHA/ASSE Z10, Occupational Health and Safety Management Systems, or
- 🥏 OHSAS 18001

Compliance shall be ensured for all the tenderer's own operations with significant responsibility for the manufacture or assembly of products.

# 29. OCCUPATIONAL HEALTH AND SAFETY OF SUPPLY CHAIN: ADVANCED

The tenderer declares that three of its six largest suppliers (by annual expenditure, fiscal or calendar year) manufacture these components in supplier facilities that are compliant or certified:

- 🥏 ISO 45001
- ANSI/AIHA/ASSE Z10
- 🥏 OHSAS 18001

if the facility is owned or operated by the supplier.

# 30. CERTIFICATION TO SOCIAL RESPONSIBILITY PERFORMANCE STANDARD: ADVANCED

The tenderer declares that all supplier-owned or operated facilities of three of its top six suppliers (by annual expenditure, fiscal or calendar year) are

- 🥏 certified to Social Accountability (SA) 8000 by accredited certification bodies; or
- 🥏 have been audited against the RBA Code of Conduct using the Validated Audit Process (VAP); or
- have adopted the RBA Code of Conduct and incorporated its requirements into their supplier processes, and regularly assess their suppliers against these requirements.

# **31. CONFLICT MINERALS RESPONSIBLE SOURCING: ADVANCED**

The tenderer conducts due diligence in good faith to identify all sources of conflict minerals used in all of its products and concludes that they originate from one of the following sources:

1) recycled or scrap sources; or

2) smelters, refiners, or both, that have been determined by the Responsible Minerals Initiative (RMI) to be compliant with the Responsible Minerals Assurance Process (RMAP) program or one of the RMI's cross-recognised assessment programs and appear on the RMI's list of validated smelters and refiners, consistent with the requirements of the OECD Due Diligence Guidance and the definitions provided in both Rule 13p-1 under the U.S. Securities Exchange Act of 1934 and Regulation (EU) 2017/821.



# 32. PUBLIC DISCLOSURE OF USE OF CONFLICT MATERIALS IN PRODUCTS: ADVANCED

The tenderer declares whether any of its products covered by the tender that it has manufactured or contracted to have manufactured contain conflict minerals that are necessary for the functionality or production of those products, and prepares disclosures on the use and sources of such minerals. Such disclosures shall be publicly available.