

The Swedish Environmental Management Council Report 2012:5

TECHNICAL REPORT – CRITERIA FOR SUSTAINABLE MEDICAL  
DEVICES

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## MISSION

The Swedish Environmental Management Council (SEMCo) is developing EU Green Public Procurement (GPP) criteria for medical devices. This is a voluntary process in agreement with the Directorate General for the Environment (DG Environment) of the European Commission.

The project is divided into two phases. During phase 1 (March 2011 – December 2013), criteria will be developed for electrical and electronic equipment used in the healthcare sector (healthcare EEE). The plan is then for criteria for consumables to be developed during phase 2 (although not those for absorbent sanitary products already subject to eco-labelling and so will be developed by the JRC, the Joint Research Centre. However, no decision has yet been made in this regard as SEMCo needs to identify funding before deciding whether to proceed with this work.

Any future EU GPP criteria for medical devices will be adopted on a national level in Sweden, possibly together with additional criteria.

## PROJECT PLAN

The project plan can be seen in Figure 1 below. This plan has been modified during the development of the project and may well undergo further modifications. The plan satisfies the requirements set out by DG Environment for the procedure<sup>1</sup> for development of EU GPP criteria. It also contains several additional steps required as part of SEMCo's criteria development process.

In parallel with the EU Stakeholder Ad Hoc Working Group (AHWG) Meetings (red boxes), meetings have been held with stakeholders and experts in Sweden (green boxes, so-called preparatory meetings). These steps have been included so that as much knowledge and input as possible is gathered for the reports and criteria and to support the AHWG meetings.

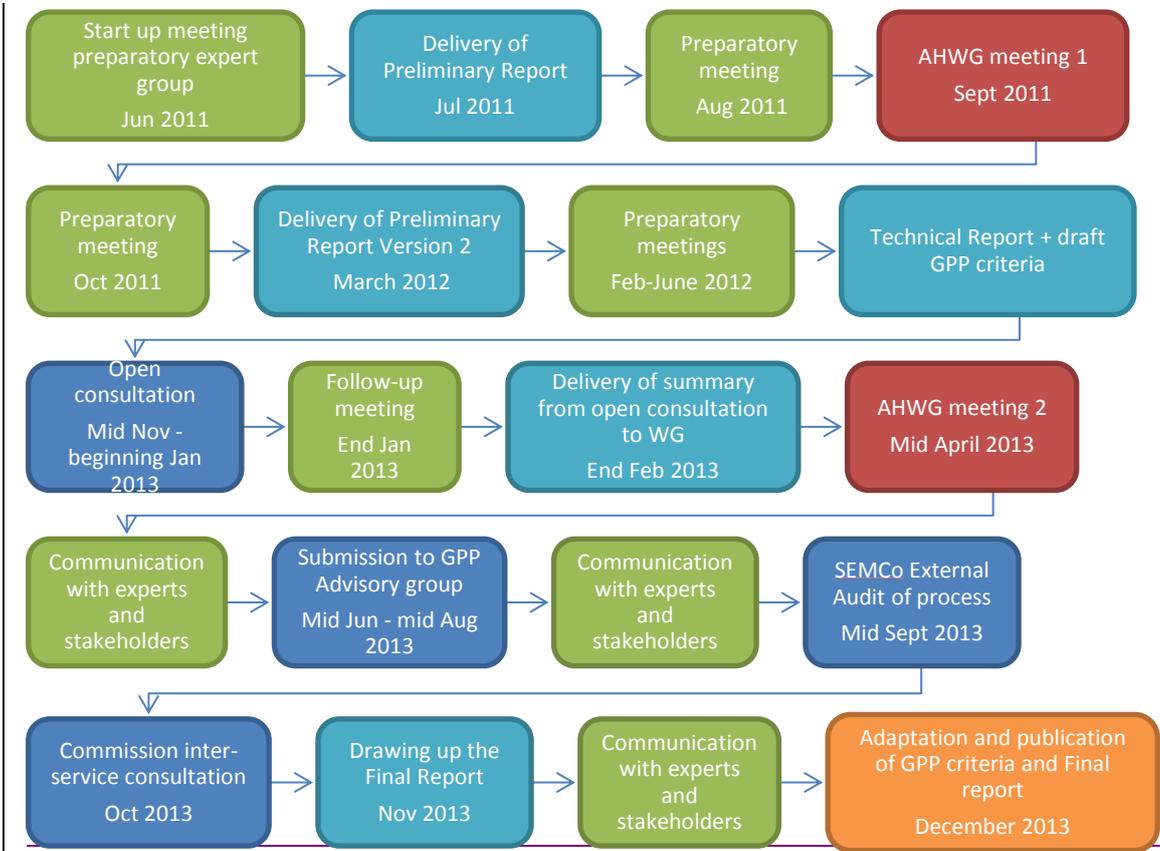
*Figure 1: Illustration of the project plan for development of GPP criteria.*

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<sup>1</sup> For the "Procedure for the development and revision of GPP criteria" please see [ec.europa.eu/environment/gpp/gpp\\_criteria\\_procedure.htm](http://ec.europa.eu/environment/gpp/gpp_criteria_procedure.htm)



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## 1 INTRODUCTION

### 1.1 THE MEDICAL TECHNOLOGY INDUSTRY

The medical technology industry is a significant contributor to the European economy; it generates annual sales of EUR 95 billion and the industry is growing at an annual rate of more than 5%.

There are almost 22 500 medical technology companies in Europe; of these nearly 18 000 (around 80%) are micro, small and medium-sized enterprises. The industry also provides a large number of high-quality jobs, employing nearly 500 000 people.

Of total sales about 8% is invested in research and development each year. The continuous cycle of investment has made Europe a centre of excellence for innovation in medical technology.

### 1.2 PROCUREMENT FOR A SUSTAINABLE FUTURE

European public authorities spend approximately EUR 2 trillion annually (equivalent to 19 % of GDP) on the purchase of goods, services and works (European Commission Environment, 2010-12-09). This means that public authorities are major consumers who can use their purchasing power to choose goods and services with a reduced environmental impact, thereby making an important contribution to sustainable consumption and production (European Commission Environment, 2010-12-09). Sustainable Public Procurement (SPP) means that when making its purchasing decisions, an organisation should take into account the environmental, social and ethical performance of the products or services being procured over their entire life cycles. Recent years have seen a positive development with regard to environmental and social criteria in public procurement. Sustainable public procurement has the potential to be an effective tool in promoting sustainable production and consumption, as demonstrated in the Europe 2020-strategy (European Commission, 2010) and the Green Paper on the Modernisation of EU Public Procurement (European Commission, 2011-04-15).

To assist public authorities and organisations seeking to contribute to a sustainable future by using “green and socially responsible procurement” the Commission and also individual Member States have developed tool kits for green public procurement (GPP) and socially responsible public procurement (SRPP) criteria.

GPP is defined as "*a process whereby public authorities seek to procure goods, services and works with a reduced environmental impact throughout their life-cycle when compared to goods, services and works with the same primary function that would otherwise be procured.*" (European Commission, 2008-07-06)

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SRPP gives contracting authorities an opportunity to make purchases in the light of social considerations and can be used to promote decent working conditions and ensure wider compliance with social standards.

The EU GPP toolkit includes GPP criteria for product and service groups in 19 sectors. Two sets of criteria are presented for each product or service group:

**Core GPP criteria** address the most significant environmental impacts, and are designed to be used with minimum additional verification or cost increases.

**Comprehensive GPP criteria** are intended for use by authorities who seek to purchase the best environmental products available on the market. They may require additional administrative effort or involve a certain cost increase compared with other products fulfilling the same function.

Since GPP is a voluntary instrument it means that individual Member States and public authorities can determine the extent to which they implement it (European Commission Environment, 2010-12-09).

This should not be confused with the procurement directive (of the European Parliament and the Council, 2004) regulating the forms and procedures for public procurement mandatory for all Member States.

## 2 THE IMPORTANCE OF GPP AND SRPP CRITERIA FOR HEALTHCARE EEE

There are several reasons why GPP and SRPP criteria should be developed for electrical and electronic equipment used in the healthcare sector (healthcare EEE); several important examples of these are provided in this chapter.

### 2.1 A LARGE ENERGY USER WITHIN HEALTH CARE

The Swedish Energy Agency has carried out an inventory of electricity consumption in 69 hospital buildings, 11 health centres, and 55 geriatric care centres in Sweden (the Swedish Energy Agency, 2008). The study shows that the energy use of healthcare EEE represents more than 15 % of total consumption, making it the third largest user in healthcare buildings, after lighting and ventilation<sup>2</sup>. This does not include the strict requirements for air quality in surgery and examination rooms, which increase the power consumption of ventilation systems.

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<sup>2</sup>The power consumption of health care EEE is divided into a number of sections in the study: medical equipment, IT, lighting, cooling etc.

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## 2.2 SIGNIFICANT AND PRIORITISED PRODUCTS

The Eco-design report, Study for preparing the first Working Plan of the Eco-design Directive (EPTA, 2007), prioritised 57 product groups to be included in the Eco-design Directive. Three (24, 25, and 26) out of the 57 product groups contain medical equipment. Products included within the scope of the Eco-design Directive have to fulfil the following requirements:

- Have significant annual sales volumes and business within the EU
- Have significant environmental impact
- Represent significant potential for improvement in terms of their environmental impact (VHK, 2005-11-28).

## 2.3 THE IMPORTANCE OF TAKING ACTION NOW

A study of the age profile of diagnostic medical imaging devices shows that the equipment installed within the EU is 10 years old and up (COCIR, 2009). Replacement is essential since this equipment is no longer state-of-the-art. If a large quantity of equipment is to be procured over the next few years, it is important that GPP criteria are developed now so that they can be used in future upcoming procurement.

## 2.4 CURRENT INITIATIVES

In fact, there are already healthcare EEE initiatives in progress within the EU , for example, COCIR has carried out a Self-Regulatory Initiative on Eco-design for Medical Imaging Equipment (COCIR, 2009-10-19).

## 2.5 ONE OF THE MOST PROCURED PRODUCT CATEGORIES

Procurement data from Sweden (starting from 2009) show that healthcare EEE is in the top 14 most procured product categories based on both economic value (in millions of SEK) and the number of procurement operations. *More information about market data is available in chapter 10.* (Swedish Competition Authority, 2011)

## 2.6 AN ENERGY-INTENSIVE PRODUCT SECTOR

Compared with other more energy-intensive product sectors, the environmental impacts associated with the energy use of medical equipment has generally been considered to be insignificant. But the conclusions of the “Study for preparing the first Working Plan of the Eco-Design Directive”, (EPTA, 2007) indicate otherwise. The aim of the study was to bring together the available information and arguments so that certain product groups could be prioritised. Its specific objectives were:

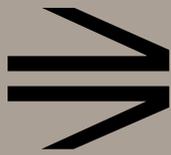
- To identify all Energy Using Products (EuPs) within the scope of the Eco-Design Directive

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- To classify all potential EuPs in product categories for further assessment through preparatory studies
- To produce a short list of prioritised EuPs that could be potentially included in the indicative list in the Working Plan

A special emphasis was placed on the collection of EuPs for which Life-cycle Assessment reports or other environmental impact assessments had been conducted. Using the results of these reports and assessments, classified categories were examined according to their environmental impact and improvement potential. The products were then ranked on the basis of a “primary energy consumption” environmental indicator since this was deemed to be one of the most consistent indicators. The aim of the study was for a final list of 25 products to be drawn up. The project team decided to draw up a list of 34 prioritised product groups, divided into priority “A” (25 products) and priority “B” (9 products) EuP categories (EPTA, 2007).

RANK	PRODUCT CATEGORY	TOTAL ENERGY (GER)	PRIORITY
1	34. IN HOUSE NETWORKING (LAN) AND DATA PROCESSING, STORING AND PROVIDING OF EQUIPMENT	31227,2218	A
2	1. TRANSFORMERS	17694,5841	A
3	4. MACHINE TOOLS (MANUFACTURING - INDUSTRIAL USE)	17475,4259	A
4	13. ELECTRIC AND FOSSIL FUEL HEATING EQUIPMENT	14383,1965	A
<b>5</b>	<b>25. SURGICAL, PATIENT RECOVERY AND MEDICAL EQUIPMENT</b>	<b>8394,97646</b>	<b>A</b>
6	18. INDUSTRIAL AND LABORATORY FURNACES AND OVENS	5934,41495	A
7	7. DOMESTIC LAUNDRY EQUIPMENT AND SIMILAR	4205,93034	A
8	3. AUTOMATIC WELDING MACHINES	3446,03916	A
<b>9</b>	<b>24. ELECTRODIAGNOSTIC APPARATUS</b>	<b>2621,39756</b>	<b>A</b>
10	35. NETWORK EQUIPMENT FOR ALL TYPES OF DATA PROCESSING (DATA, TELECOMMUNICATION, INTERNET, MOBILE AND RADIO NETWORK EQUIPMENT)	2468,6856	A
11	10. POWER ELECTRONIC PRODUCTS (INVERTERS, STATIC CONVERTERS, INDUCTORS, SOFT STARTERS)	1644	A



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RAN K	PRODUCT CATEGORY	TOTAL ENERGY (GER)	PRIORITY
12	28. SOUND AND IMAGE PROCESSING MACHINES AND EQUIPMENT	1574,66387	A
13	6. FOOD PREPARATION EQUIPMENT, DOMESTIC AND HOUSEHOLD USE	1324,23774	A
14	15. REFRIGERATION EQUIPMENT	914,70613	A
15	14. AIR CONDITIONING SYSTEMS AND HEAT PUMPS	813,328553	A
16	9. ELECTROMECHANICAL HAND TOOLS	723,37471	A
17	2. MEASURING TRANSFORMERS	682,392622	A
18	36. AERIALS, ANTENNAS, RADARS, RADIO NAVIGATION AND CONTROL SYSTEMS	487,007999	A
19	16. LIFTING, MOVING AND LOADING EQUIPMENT	263,282671	A
20	48. ATMS AND TICKETING MACHINES	253,997441	A
21	29. SOUND PROCESSING MACHINES AND EQUIPMENT (INCLUDING RADIO EQUIPMENT)	241,995107	A
22	54. OTHER MOTORS OR MOTOR DRIVEN EQUIPMENT NOT COVERED BY THE ABOVE CATEGORIES	140,211164	A
<b>23</b>	<b>26. HIGH ENERGY DIAGNOSTIC AND MEDICAL EQUIPMENT</b>	<b>124,204694</b>	<b>A</b>
24	42. LIGHTING INSTALLATIONS NOT COVERED BY EXISTING LOTS	120,907817	A
25	17. FOOD PRODUCTION EQUIPMENT	113,64764	B
26	8. VENDING MACHINES FOR BEVERAGE AND GOODS	104,085921	B
27	11. COMPRESSORS	88	B
28	39.A) END EQUIPMENT FOR DATA USE AND COMMUNICATION WITH OPTION OF NET CONNECTION	77,1767879	B
29	51. MOTOR-DRIVEN EQUIPMENT FOR WASTE WATER TREATMENT, HOT WATER AND CHEMICAL PROCESS	69,0102801	B
30	5. MACHINES FOR PERSONAL CARE	48,8555498	B
31	52. VENTILATION EQUIPMENT FOR UNDERGROUND INFRASTRUCTURES AND SPECIAL PROCESSES	18,4027414	B

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RANK	PRODUCT CATEGORY	TOTAL ENERGY (GER)	PRIORITY
32	43. MOWERS		B
33	30. BOILERS		B
34	31. GENERATING SETS USING FOSSIL FUELS		B

*Table 1: Prioritised EuPs according to the “Study for preparing the first Working Plan of the Eco-Design Directive” (EPTA, 2007)*



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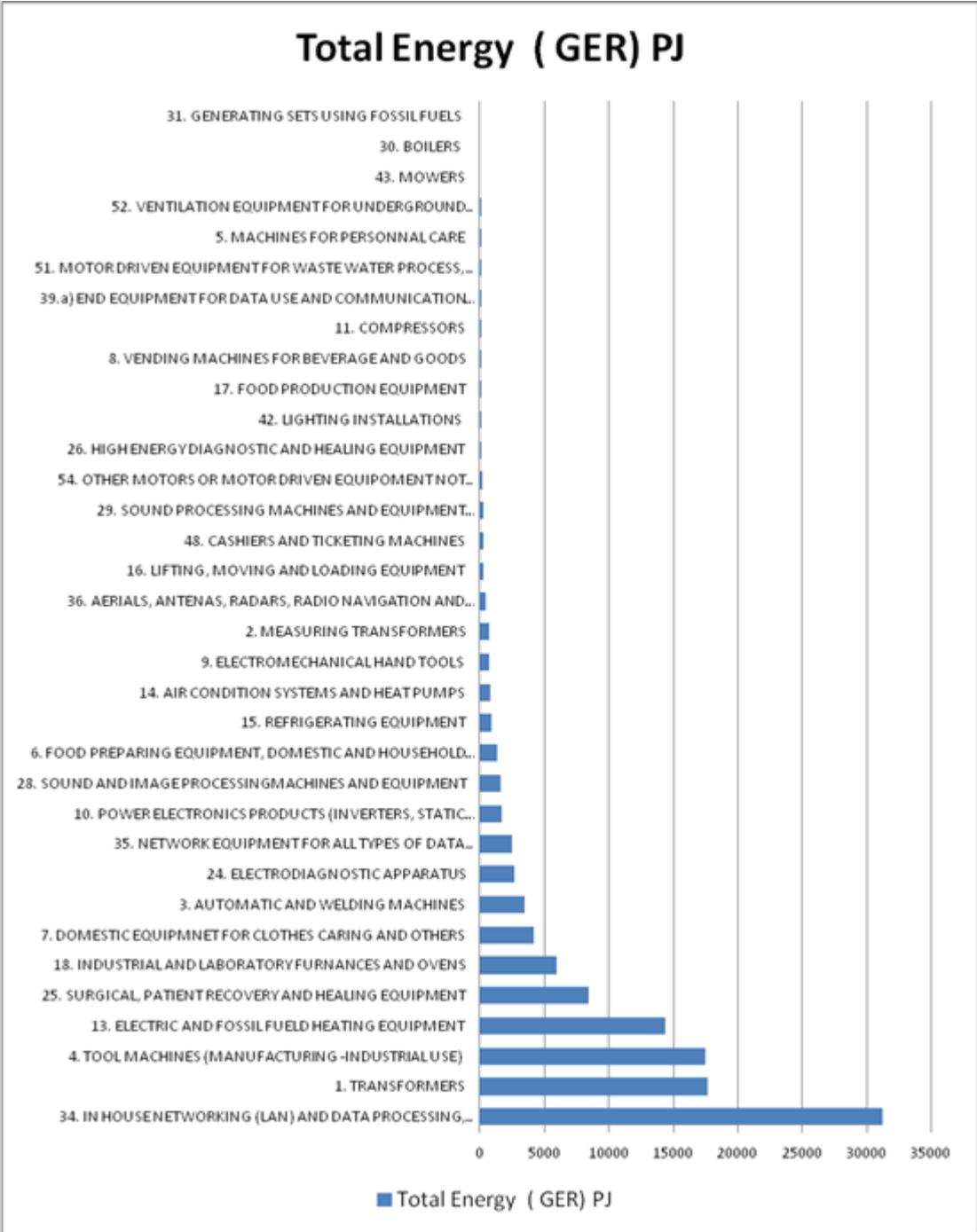


Figure 2: Energy consumption of prioritised EuPs.

Medical equipment is classified in groups 24, 25 and 26 plus part of group 35 (since information technology used in medical care is used for medical equipment and thus should be classified as medical equipment.) Medical equipment is in the top five of the highest energy using products in the EU.

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## 2.7 RAPID ADVANCES IN TECHNOLOGY

The term “medical technology” means the technology applied to diagnostics and therapy within a healthcare setting. Medical technology uses and applies the latest findings within technology to develop instrumentation, sensors, donors, diagnostic and treatment devices, medical imaging systems, artificial organs and other medical systems. The aim is to develop more patient-friendly, safer and more reliable methods throughout the entire patient pathway (prevention, diagnostic, therapy and care). Rapid advances in healthcare technology result in the introduction of increasing amounts of equipment, new equipment and equipment with more complex functions – all of which increase the energy consumption of medical equipment in healthcare settings. This is also linked to the factors described in chapter 2.8 below.

## 2.8 AN INDUSTRY EXPANDING AS A RESULT OF NEW POPULATION AND SURVIVAL TRENDS

The report “IEC SMB/4136/R” states that the rapid expansion of medical services and the application of electrical medical equipment are due to:

- the population’s greater life-expectancy ,
- significant population growth,
- increased impact of information technology,
- new technologies such as bioengineering ,
- developing countries are generating new equipment markets,
- cost-cutting is becoming increasingly important in medicine

### 2.8.1 HIGHER SURVIVAL RATE

A report from SLL, Stockholm County Council (Stockholm County Council) “Long-term survey of healthcare in SLL, 2008- 2025, March 2009” states :

The development of technology has contributed to better healthcare by making the diagnosis and treatment of increasing numbers of difficult diseases a possibility. Over the past 10 years this development has been very substantial and is expected to continue, probably at the same rate, mainly in the case of imaging systems but also in cancer therapy, instrument systems and implantable appliances. This results in higher survival rates in the population.

For example, cancer mortality has fallen because of preventive efforts, early diagnosis and better treatment. The number of diagnosed patients living with cancer has increased and is expected to go on increasing because of the population growth and the rapid growth in the aging population: 98% of prostate cancer patients survive today compared with almost zero % 25 years ago, according to Physician and Associate Professor Eva Cavallin-Ståhl at the University hospital of Lund.

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## 2.8.2 AN AGEING POPULATION

In ten years' time two-thirds of Europe's population will be over 50 years of age.

In Sweden, the total number of outpatients (OPD) in SLL has almost doubled over the last 10 years, from 8 to 16 million. This represents an average annual increase of 8%. The number of 65-74 year olds is going to increase by more than 50% and the number of over 85 year olds will increase by 10% between 2005 and 2014. The report indicates that the numbers of patient visits are likely to increase: over the next five years A and E visits will increase by approximately 7% and geriatric visits will increase by 6% (Stockholm County Council). This forecast does not take account of the growth in medical devices with their new diagnostic methods with increasingly complex functions which will result in better and earlier diagnosis, more effective and successful patient treatment and completely new treatments.

## 2.8.3 DEVELOPING COUNTRIES

Older and sicker populations will push up healthcare costs dramatically in China, India and elsewhere over the coming years. In developing countries as a whole, just 8% of the population is currently aged 60 years or over but by 2050, 20% of their population is expected to be in that age range. Moreover, as populations in emerging economies adopt western lifestyles and diets, chronic diseases will begin to affect and claim more lives (Philips, 2007).

## 2.8.4 CONCLUSIONS

A growing ageing population with higher survival rates in combination with the high rate of development within medical technology is leading to more, better and earlier treatments which in turn is resulting in the use of more equipment and automation and thus higher energy consumption within health care.

Technological developments contribute to improved medical care by providing diagnosis and treatment of a larger number of difficult diseases. However, across the globe and also in Sweden, there is increased demand from decision-makers for cost savings to be made in health care, including in investments in medical technology and energy efficiency. (SLL, 2009)

## 2.9 MAJOR FUTURE INVESTMENTS

The new Karolinska Hospital currently being built in Solna will have 700 beds, 36 operating theatres and numerous health departments such as paediatric, cancer, inflammatory diseases, neurology, cardiovascular and reparative medicine. The whole building will have between 9 and 11 floors, cover 320 000 m<sup>2</sup> and require about 240 kWh of energy per m<sup>2</sup> per year. Cyclotrons, PET/CT cameras and MR cameras are a few examples of the equipment that is to be procured, Approximately SEK 2.5 billion is going to be invested in the medical equipment (not including laboratory equipment) for this hospital. Such a huge investment will provide procurers with the opportunity to choose more

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environmentally-friendly products, contribute to the development of greener products and minimise energy usage by using green procurement criteria to achieve its ambition to be a green hospital<sup>3</sup>.

It is therefore important to act now and ensure that the GPP criteria are ready for when these investments are made.

## 2.10 ENSURING BETTER WORKING CONDITIONS

The need for corporate social responsibility (CSR) has increased in line with the globalisation of markets: social responsibility is now increasingly becoming an integral feature of the daily operations of both large and small companies. The fact that businesses are assuming social responsibility is nothing new; however, the greater focus on CSR is a direct result of increased globalisation.

Responsible supply chain management focuses on collaborating with suppliers to ensure decent working and environmental conditions. This is particularly important for companies using suppliers in countries where national legislation and internationally recognised principles and standards relating to human rights, employment standards, the environment and anti-corruption are not fully respected. Working conditions in the supply chain are usually required to be subject to ILO core conventions, the UN Convention on the Rights of the Child and basic health and safety regulations and employment law.

The public sector has the option to include social aspects in their procurement activities and use public procurement as an instrument to achieve improvements in working conditions in supply chains. The public sector can use tax payers' money responsibly to include social criteria when procuring. It is also crucial that the public sector sets a good example for others.

## 3 SELECTION OF SCOPE

Since a huge range of electrical and electronic equipment is used in the healthcare sector (Healthcare EEE) the project's scope needed to be narrowed down. This chapter explains the principles for the selection of the scope.

### 3.2 PRIORITY PRINCIPLES

The general principles for a product to be prioritised were as follows:

1. The equipment had to be classified as a Medical Device, as defined in the Medical Devices Directive 93/42/EEC (MDD)
2. The equipment had to have a high energy consumption compared with other types of equipment

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<sup>3</sup> <http://www.nyakarolinskasolna.se/sv/>

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### 3. Large volumes of the equipment had to be in use (and therefore represented a high total energy consumption)

These principles are mainly based on the environmental aspect analysis (see *chapter 6 Environmental aspects*) which showed that the most significant environmental aspect is the energy consumption during the product's use phase. Basing the selection on chemical content or social aspects, for example, was found to be ineffectual since these aspects were assumed to be similar across various types of products used within healthcare EEE. Prioritisation would not be based on the medical device's risk classification.

The project's time constraints dictated that its scope had to be restricted; laboratory/in-vitro equipment, dental equipment and implants were therefore excluded from the beginning.

#### 3.2.1 DEFINITION OF A MEDICAL DEVICE

Under the Medical Devices Directive 93/42/EEC (MDD) a 'medical device' is defined as any instrument, apparatus, material or other article, whether used alone or in combination, including software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

#### 3.2.2 ELECTRICAL AND ELECTRONIC EQUIPMENT USED IN HEALTH CARE

Electrical and electronic equipment used in the healthcare sector includes both high and low voltage equipment. It covers the complete care cycle (prevention, diagnostic, therapy and care). According to the standard IEC 60601-1 medical electrical equipment is defined as:

##### **2.2.15 Medical Electrical Equipment** (hereinafter referred to as Equipment)

Electrical **Equipment**, provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient. The equipment includes those

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accessories as defined by the manufacturer which are necessary to enable the normal use of the equipment.

### 2.2.16 Mobile Equipment

Transportable **Equipment** intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

## 3.3 DRAWING UP THE PRIORITISATION LIST

To select the relevant equipment according to the principle of '**volume**' the inventory system at Karolinska University Hospital and Uppsala Academic Hospital were studied. The first selection list was then discussed with medical engineering experts and procurers from several Swedish County Councils, Regions and hospitals (Uppsala, Stockholm/Karolinska, Östergötland, Halland, Kalmar, Skåne, Gotland and Västra Götaland). To select relevant equipment according to the principle of '**high energy consumption**' the COCIR Eco-design study for Medical Imaging Equipment (COCIR, 2009-10-19) was consulted. In addition, medical engineers helped us identify high and low energy use in equipment other than imaging equipment.

Other studies were also consulted to confirm that the selection was reasonable and to ensure that no important equipment had been omitted:

- The Swedish Energy Agency's project STIL2 (The Swedish Energy Agency, 2008) was consulted. The project comprised measuring and calculating the energy consumption in hospital buildings across Sweden. Medical equipment pinpointed in the project was prioritised.
- HCWH, the NHS in the UK and Energy Star in the USA have reported certain items of equipment as being energy consuming and these were prioritised.
- There is little market data available, but data from PRODCOM for 2009 were gathered and compiled: see chapter 10. Data from PRODCOM for year 2006 is provided in the Eco-design report Study for preparing the first Working Plan of the Eco-design Directive, Annex 15 (EPTA, 2007). A problem is that the PRODCOM codes have changed over the years and are difficult to compare. The preliminary evaluation was that the prioritisations made sufficiently matched the volumes, though it was difficult to assess whether some of the prioritised product categories had been included in the PRODCOM codes or not.

The final prioritisations proposed were checked with the Swedish Medical Equipment Trade Association (Swedish Medtech), as well as industry stakeholders, procurers, authorities, and the medical engineering and medical professions (June 14 2011);, see the list of stakeholders (chapter 4). The scope proposed was also checked with European stakeholders at an AHWG meeting in Brussels on 20 September 2011.

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This resulted in discussions regarding the exclusion of Cathlab, medical refrigerators and IT for medical equipment. The classification of medical information systems is still in progress; it was therefore suggested that IT be excluded. Regarding Cathlab, stakeholders emphasised that few Cathlabs are used in health care. It was suggested that medical refrigerators be excluded as it is not clearly defined which refrigerators are medical and which are non-medical.

Stakeholders proposed that not only should installed equipment be included but mobile equipment as well (e.g. mobile X-ray equipment) even though its energy consumption (5 KVA) is much lower than that of fixed installations (40 KVA) (EPTA, 2007), since a large amount is currently in use and this is increasing.

Stakeholders also proposed that fume cupboards, safety beds and laminar airflow systems be included because of the rapid increase in the numbers of these systems. Laminar airflow systems were eventually excluded as few are procured. Fume cupboards and safety beds are used in a laboratory environment, which falls outside the scope of this project.

### 3.3.1 PRIORITISATION LIST

The following product categories were proposed for inclusion in the scope of this project:

1. Anaesthesia equipment
2. Autoclaves and disinfectant equipment
3. CT (Computed Tomography)
4. Dialysis equipment
5. Diathermy equipment
6. ECG equipment
7. Endoscopic equipment
8. Incubators for babies
9. Infusion pumps and syringe pumps
10. Intensive care equipment
11. Linear accelerators
12. Medical and surgical lighting
13. Medical freezers
14. Monitoring equipment
15. MRI (Magnetic Resonance Imaging)/MRT (Magnetic Resonance Tomography)
16. Patient warming systems

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17. PET (Positron Emission Tomography)/SPECT (Single-Photon Emission Computed Tomography)

18. Surgical lasers

19. Ultrasound

20. X-ray (incl. mammography)

The list might change as the project progresses. A description of the equipment can be found in Appendix III.

#### 4 STAKEHOLDERS

The following group of stakeholders were involved in the drawing up of GPP criteria for electrical and electronic equipment used in the healthcare sector:

- Trade associations
- Individual companies
- NGOs
- Procurers and purchasing organisations within health care
- Medical Engineering
- Energy Agencies
- Medical Product Agencies
- Chemicals Agencies
- Medical professions
- Environmental experts within healthcare
- Ministry experts
- Testing experts

For a detailed list of stakeholders, see Appendix II.

Our aim was to invite stakeholders that cover the whole cycle i.e. from manufacturers and procurers/procurement teams to end-users in the operating environment. This was done in order to ensure a balance between health and safety on the one hand and the applicable environmental requirements without any health and safety implications on the other.

The stakeholders and experts were consulted at the 25 meetings held and by means of several telephone conferences, e-mails, forum on SEMCo's website and personal telephone calls.

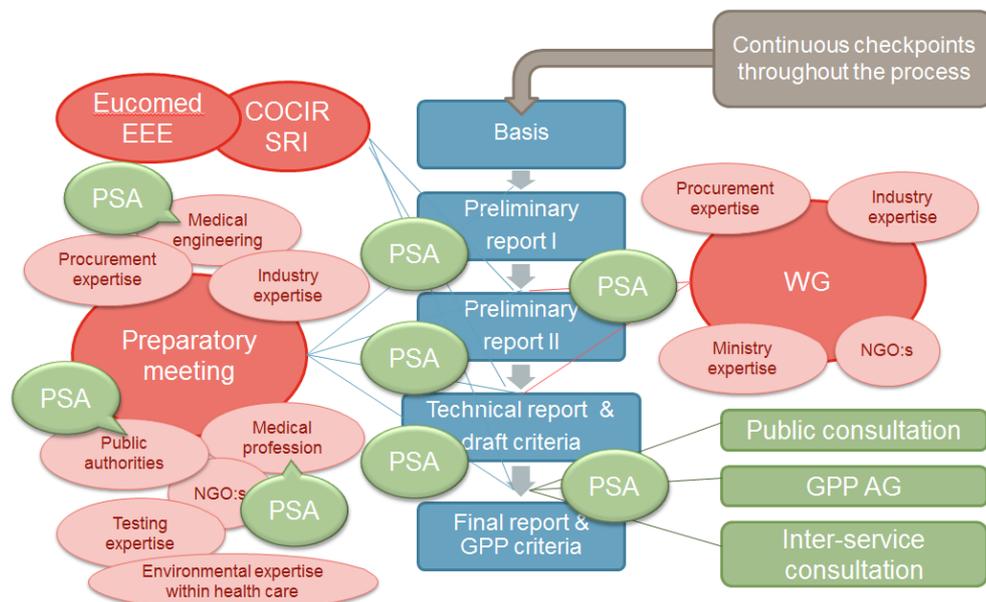
Stakeholders who did not attend meetings were encouraged to participate in the open consultation.

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## 5 PATIENT SAFETY ASPECTS

Due to the nature of electrical and electronic equipment used in the healthcare sector patient safety aspects will always take priority over any other aspect in the development of criteria for sustainable procurement. Healthcare EEE-related legislation, standards and labelling always take patient safety into consideration so that whenever other standards are used or referred to in the criteria, stakeholder dialogue will ensure that there are no conflicts with patient safety, which will be a consistent check point throughout the development process and also when decisions are taken.

Read more about this in Chapter 11, The Criteria Development Process.



*Figure 3: Stakeholder dialogue process showing how patient safety aspects (PSA) are taken into consideration throughout the criteria development process.*

## 6 ENVIRONMENTAL ASPECTS

An environmental aspect is an element of an organisation's activities or products or services that can interact with the environment while an environmental impact is any change to the environment, whether adverse or beneficial, wholly or partially resulting from an organisation's environmental aspects (ISO 14001).

### 6.1 PURPOSE AND AIM

The purpose of this part of the study was to identify the significant environmental aspects of electrical and electronic equipment used in the healthcare sector (healthcare EEE) and then to use the conclusions in order to

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prioritise the most significant impacts as a basis for developing green public procurement criteria.

## 6.2 METHOD

To identify the most significant environmental impacts an analysis of life-cycle related information was carried out. However, no publicly-available life-cycle analyses covering all healthcare EEE were found. The LCA-related information obtained relates to individual categories of healthcare EEE; there is also a considerable lack of data for certain healthcare EEE within the scope of the project. An attempt was made to find comparable LCAs for this equipment, in order to find similarities and use this to make assumptions.

One assumption was that more detailed information is likely to be obtainable from individual companies., A question regarding LCA-related information and a question regarding chemicals were therefore included in the RFI (Request For Information/Questionnaire) sent out to the companies and trade associations. (*Read more about the RFI in chapter 10 Market analysis*).

### 6.2.1 STUDY OF THE LCAS

The comparable LCAs found were within the preparatory studies for the Eco-design Directive, and the comparisons were checked with industry stakeholders (2011, June 14). The Eco-design Directive sets out requirements for these preparatory studies one of which is intended to provide an environmental impact assessment and environmental analysis based on LCI data and LCA databases or LCA documents. The functional unit is specified according to the ISO 14050 standard.

For the environmental analyses, the Eco-design preparatory studies use data sources such as:

- Full LCA tools (SimaPro 6, Gabi 4, etc.), LCA databases (Ecolavent 2003, etc.), LCA weighting methodologies (Eco-indicator 99, etc.)
- Simplified LCA tools (Eco-it, LIME, etc.)
- Background reports from EU environmental and energy-related legislation
- Industry associations supplying emission and consumption data (APME, IISI, etc.)
- BOM – Bill-of-Materials, etc.

A common synthesis of LCA-related information from the Eco-design preparatory studies is GER – Gross Energy Requirements – plotted in tables and diagrams across all life-cycle stages. This term is used to provide equivalents for primary energy consumption for the entire process chain (VHK, 2005-11-28) (VHK, 2005-11-28).

Another comparison was made between healthcare EEE that have similar technical components. For example, no data were found for mammography

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equipment but were found for X-ray equipment. It was therefore possible to assume that mammography equipment has the same significant environmental aspects as X-ray equipment.

Certain LCA databases such as the European Reference Life-cycle Data Systems (ELCD), Gabi, and CMP (Competence Centre for Environmental Assessment of Product and Material Systems) were consulted but as these their LCA-data relates to raw materials i.e., mainly components, i.e. not for whole products, they were of little value given the project's time-constraints.

The MECO (Material, Energy, Chemicals and Others) method was also investigated in order to identify a "simple" LCA-method for our purpose, but even this was found to be too time-consuming, as access was needed to all product-level data and relating to materials, energy, etc., which had a significant environmental impact. This method focuses on the life-cycle stages of material supply, manufacture, use, disposal and transport of the product.

No preparatory studies have been carried out for voluntary labelling such as EU-Eco label, Nordic Swan or Blue Angel as no eco-labels exist for healthcare EEE.

Databases of scientific journals were examined. A few articles were found covering the carbon footprint of certain medical systems and modalities and treatment regimes.

Trade associations were contacted, but no LCA-related information was found. The European trade association COCIR, however, has conducted a preparatory study for a Self-Regulatory Initiative in accordance with Eco-design.

Company LCA-related information was found that provided equivalents for primary energy consumption for the entire process chain using CED – Cumulative Energy Demand. Other types of documents found useful were PEP (Product Environmental Profile) and EPD (Environmental Product Declaration).

In addition, the standard IEC 60601-1-9 gives examples of environmental aspects of healthcare EEE in general that can be identified across all life-cycle stages.

To summarise, information for this analysis of environmental aspects and impacts was obtained from various sources:

- Eco-design preparatory studies
- PEP, LCA according to ISO standard
- EPDs, CED method
- Scientific journals
- Other reports

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## 6.2.2 IDENTIFYING HAZARDOUS CHEMICALS

The process for developing EU GPP criteria includes a requirement to identify hazardous substances that are of relevance to the product group. LCA methods for electrical and electronic equipment seldom include any hazardous chemicals assessment or chemicals risk analyses. A complementary study was therefore carried out to ensure that all possible hazardous chemicals relevant for healthcare EEE were identified.

To the author's knowledge, no reports on the chemicals found in healthcare EEE are available. As electro-technology is mostly produced in the same factories and countries, it is assumed that chemicals used in healthcare EEE are comparatively the same as in other EEE. The Swedish Environmental Management Council's report "*Chemicals in electrical and electronic equipment*" (Christiansson, 2010) identifies a number of hazardous chemicals used in EEE. This report has therefore been used as a basis for our study. The report has sources such as:

- A report from ÖKO-institute in Germany on behalf of the EU Commission about hazardous substances in electronics, not regulated by the RoHS Directive (Öko-Institut e.V, 2008).
- Various companies' own chemicals lists regarding the phasing out of hazardous chemicals
- A report from the Swedish Environmental Protection agency concerning hazardous substances in electronic waste (Lundstedt, 2011-03)
- Reports from NGOs such as Greenpeace and SwedWatch
- Scientific publications
- Contacts with recycling companies in Sweden
- Contacts with manufacturing companies

As mentioned in the introduction, issues about chemicals, such as if current equipment complies with RoHS or if equipment contains substances included in the REACH Candidate list or other specified hazardous substances (see Appendix V), has been outlined in the RFI that was sent out to companies. The purpose of these questions was partly to get a better understanding of which substances had been identified by individual companies as hazardous and partly which substances could be subject to criteria. The thesis "*Expanding the Scope of the RoHS Directive – Prospects and obstacles*" (Segerkvist, 2005), which is a study on knowledge and attitudes towards RoHS among companies in the medical devices sector, was also consulted.

The following information was used for our prioritisation exercise:

- Classification
- Volumes
- Information about upcoming legislation

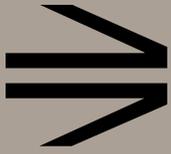
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- Information from scientific journals
- Available information on hazards and risks during production, use and at end-of-life

## 6.3 RESULTS

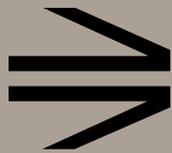
### 6.3.1 SUMMARY OF ENVIRONMENTAL ASPECTS AND IMPACTS OF HEALTHCARE EEE

Table 2 shows the environmental aspects and corresponding impacts as a summary of all data for all the healthcare EEE included in this preliminary report. Green fields are an indication of prioritisation and should be included as a basis for GPP criteria; yellow fields are also important but a decision on whether to include them or not requires further debate. Grey fields are important environmental aspects, but were examined during phase 2. The summary is based on the available LCA information. Very few results from the RFI were available so no results regarding environmental aspects could be used from the information collected.



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PHASE	ENVIRONMENTAL ASPECT	COMMENTS	ENVIRONMENTAL IMPACT
<b>MANUFACTURING AND DELIVERY</b>	Materials and component provision for manufacturing	Choice of material, reduction of material, energy usage for production of materials and components etc.	Global warming potential, acidification potential, use of natural resources, hazardous chemicals
	Emissions to air and discharge to water		Low environmental impact
	Transport		Low environmental impact
	Packaging		Low environmental impact
	Waste from production		Low environmental impact
<b>USE PHASE</b>	Energy usage	The use of electricity. Cooling of heat emissions, cooling of equipment rather than cooling of room recommended (Gullberg, 2008)	Global warming potential, acidification potential
	Water usage		Eco system services, resource usage
	Detergent consumption		Eco toxicity, eutrophication (phase II of project)
	Use of Consumables		High environmental impact, but not part of scope (phase II of project)
	Use of refrigerants with high GWP		Global warming potential



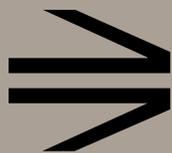
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	Helium and other gas use	Energy consumption due to liquid helium production, resource usage, GWP of N <sub>2</sub> O etc.	Global warming potential, acidification potential
	Use of hazardous chemical substances	For example, Beryllium.	Various, for example, carcinogenic impact.
<b>END-OF-LIFE</b>	Waste		Low environmental impact due to high recyclability

Table 2: Summary of environmental aspects and corresponding impacts of healthcare EEE.

Table 3 shows categories of healthcare EEE's environmental aspects. For a number of healthcare EEE, no data at all or only unsatisfactory data were found. "No data" is displayed in these cases.

PRODUCT	ENERGY USE/ USE PHASE	COMPONENT PRODUCTION/ MANUFACTURING PHASE	OTHER / USE PHASE
<b>Anaesthesia</b>	X	No data	Consumables, gases
<b>Autoclaves/disinfectant</b>	X	No data	Water, detergents
<b>CT</b>	X	X	
<b>Dialysis</b>	X	No data	Water, consumables
<b>Diathermy</b>	No data	No data	Consumables
<b>ECG</b>	No data	No data	Consumables
<b>Endoscopic equipment</b>	No data	No data	No data
<b>Incubators for babies</b>	No data	No data	No data
<b>Infusion/syringe pumps</b>	X	No data	No data
<b>Intensive care equipment</b>	No data	No data	Consumables
<b>Linear accelerators</b>	No data	No data	No data
<b>Medical and surgical lighting</b>	X	X	
<b>Medical freezers</b>	X	X	Refrigerants



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PRODUCT	ENERGY USE/ USE PHASE	COMPONENT PRODUCTION/ MANUFACTURING PHASE	OTHER / USE PHASE
<b>Monitoring equipment</b>	X	X	No data
<b>MRI</b>	X	X	Helium consumption
<b>Patient warming systems</b>	No data	No data	No data
<b>PET/SPECT</b>	No data	No data	No data
<b>Surgical lasers</b>	No data	No data	No data
<b>Ultrasound</b>	X	X	Possibly consumables
<b>X-ray</b>	X	X	

*Table 3: Summary of categories of healthcare EEE's environmental aspects.*

The examples of environmental aspects of healthcare EEE in general that can be identified across all life-cycle stages given in the standard IEC 60601-1-9 are similar to the ones identified in the LCA information studied:

- Use of hazardous substances
- Emissions to air
- Releases to surface water and ground water
- Waste, especially hazardous substances
- Use of natural resources, energy and raw materials
- Noise, vibration, odour, dust, electromagnetic fields etc.
- Transport (both for goods and services and employees)
- Risks from environmental accidents and environmental impacts arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations
- Use and contamination of the biosphere

#### Chemicals identified

The substances identified as being of potential concern for healthcare EEE can be seen in table 4 (see abbreviations in Appendix I). The table gives information on the hazards and use of the identified substance, and also

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indicated whether the substance is regulated, present on an existing “chemical list” and/or is identified in other studies and reports.

**REACH Candidate List** – Substances of Very High Concern that might be subject to authorisation. Suppliers of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) have to provide sufficient information to ensure safe use of the article by their customers on request.

**REACH Authorisation List** - Substances of Very High Concern that cannot be placed on the market or used after a given date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation.

**REACH Restriction List** - Restrictions may limit or ban the manufacture, placing on the market or use of a substance.

**Current RoHS substance** – the use of mercury, cadmium, lead, hexavalent chromium and the flame retardants PBB and PBDE in medical devices will be regulated in by 2014.

**Have been proposed for the “new RoHS”** –Substances commonly used in electronics whose hazardous properties have been identified for possible inclusion in the “new” RoHS directive in 2009/2010.

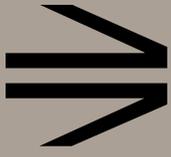
**Fulfilling PBT and/or vPvB criteria** – PBT and/or vPvB substances found in the EISIS database (JRC, 2012)

**Identified in LCA-related studies** – substances that have been indicated by companies in their LCA studies

**SEMCo report on Chemicals in EEE** – substances that are generally present in EEE and have hazardous properties

**Potential endocrine disrupter list** – substances with endocrine disrupting properties identified in the revised report to DG Environment and produced by DHI Water and Environment. (DHI, 2012)

These are all substances that are present in electrical and electronic equipment; they are assumed to also be present in healthcare EEE. Due to the fact that the responses to the RFI were very few, no information is available to ascertain whether or not this assumption is correct, whether some substances have already been substituted, or whether they ever existed in healthcare EEE. Detergents are also identified as chemicals of concern, but since consumables fall outside the scope of this project they will not be subject to criteria development.



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SUBSTANCE/ GROUP	REACH Candidate List	REACH Authorisation List	REACH Restriction List	Current RoHS substance was proposed for new	Polishing, grinding, buffing	Maintained in ENEC database	Substance report chemicals in	Substance engineering disruptor	HAZARD	USE
Antimony trioxide				x					Carcinogenic properties	Flame-retardant plastic
BBP, DBP, DEHP, DIBP	x	x		x				x	Toxic for reproduction	Softener
Beryllium /Beryllium oxide				x		x			Carcinogenic	Alloy, corrosion protection. Beryllium oxide is identified as a critical substance to phase out/minimizing MRI, CT and X-ray.
BPA				x				x	Reprotoxic properties	Production of polycarbonate, epoxy resin, epoxy plastic and in PVC
Cadmium				x					Hazardous to the water environment	
Chromium (VI) trioxide				x					Carcinogenic. Mutagenic and reprotoxic properties.	
Diarsenic trioxide	x	x		x					Carcinogenic, hazardous to the water environment	As fining agent in glass manufacturing and ceramic glass. Copper foil in circuit boards.
DIDP, DINP, DNOP			x					x	Endocrine disrupting properties	Softener
Dinickel				x					Carcinogenic	Pigment. Metal alloys in





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## Waste and recycling

Judging from the currently-available LCA-related information, healthcare EEE seems to have high recycling potential since the equipment contains high amounts of metals.

The WEEE Directive includes healthcare EEE. Medical equipment (category 8) is usually only collected through Business to Business (B2B) channels. The B2B appliances are usually already subject to bilateral agreements between customers and recyclers. As a result, a report concerning the review of the WEEE Directive ascertained that there was no reason to introduce recycling targets for medical equipment from an environmental or economic impact perspective (United Nation University, 2007-08-05).

The above information indicates that waste treatment of healthcare EEE as a significant environmental aspect does not warrant any further consideration in the development of GPP criteria.

There are also numerous opportunities for safe and high-quality refurbishment of healthcare EEE, with refurbishment being defined as “a systematic process that ensures safety and effectiveness of the medical equipment without significantly changing the equipment’s or system’s performance, safety specifications and/or changing intended use as in its original registration”.

Together with JIRA and MITA, trade associations in Japan and the United States, the European trade association COCIR has developed a good refurbishment practice guide (COCIR, 2009) for medical imaging equipment. Refurbishment would be interesting to consider in the development of GPP criteria, since the current analysis of environmental aspects based on the available LCA-related information obtained so far shows that component and material provision in the manufacturing phase could be a significant environmental aspect.

## Transport

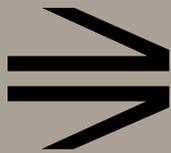
The environmental impact of transport is generally low from a life-cycle perspective. This applies to all healthcare EEE within our scope apart from MRI in which transport is an important impact, see 6.3.2 MRI.

### 6.3.2 ENVIRONMENTAL ASPECTS AND IMPACTS OF EACH EQUIPMENT CATEGORY

An overview of the information found (or otherwise) for each individual category of healthcare EEE is provided below in alphabetical order.

#### Anaesthesia equipment

Anaesthesia consumables and gasses are outside the scope of this preliminary report, but they will be examined during phase II of GPP criteria for healthcare products. However, anaesthesia gases such as desflurane, sevoflurane and



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isoflurane and laughing gas (N<sub>2</sub>O) have a global warming impact; low-flow anaesthesia could therefore be a possible recommendation, thereby affecting the equipment criteria (Axelson, 2008).

A scientific article provides information on anaesthetic room monitors. A total of 332 860 kWh of electrical power, equivalent to 178 tonnes CO<sub>2</sub> emission could be saved each year with the simple expedient of turning off anaesthetic room machine monitors when not in use. Other contributions to energy reduction could be considered: turning off theatre anaesthetic machine monitors between cases (provided this does not require machine recalibration); avoidance of Tec 6 vaporisers; and procurement or recommissioning of 'minimally electric', efficient anaesthetic machines when being replaced (Chakladar, 2010)



*Figure 4: Anaesthesia equipment.*

#### Autoclaves and disinfectant equipment

No LCAs have currently been identified for autoclaves and disinfectant equipment. However, an Eco-design preparatory study has been carried out for commercial dishwashers. Even though dishwashers are obviously not the same electrical equipment as disinfectant equipment, the results of the Eco-design LCA for dishwashers can be comparable to disinfectant equipment since these contain the same type of electronics and have similarly consume water and detergent, apart from the apparent energy consumption. It could therefore be assumed that the results of life-cycle environmental impacts of disinfectant equipment would be similar to those of the commercial dishwashers included in the Eco-design study. This showed that energy consumption, water consumption and detergent consumption in the use phase are the most significant environmental aspects. The use phase is the main contributing phase for most environmental indicators, especially energy consumption (and electricity consumption, over 97% of the total impacts), GWP and acidification. The contribution of this phase is mainly due to the amount of electricity needed

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to run the appliances during their whole lifetime. The high detergent consumption induces eutrophication impacts and the water consumption results in use of water (Öko-Institut e.V, 2010-10).

### 6.3.3 CT

See also information under heading *General information for MRI, CT and X-ray*.

Using the CED method, the result shows that the most of the total energy in the lifecycle is consumed during the use phase, over a ten-year period. See figures below., The most significant environmental aspect is therefore the energy consumption during the use phase, followed by the energy consumption during manufacturing/delivery.

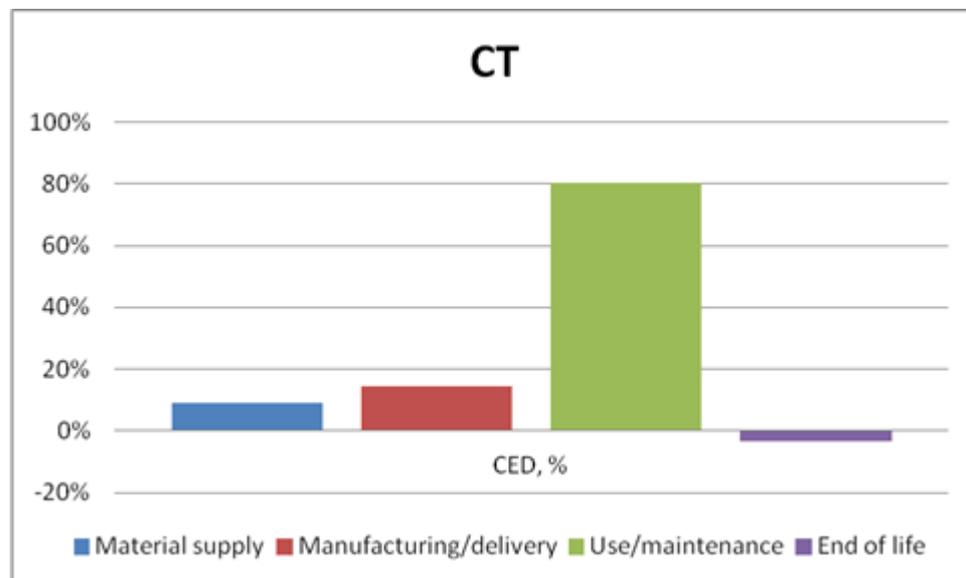


Figure 5: Example of CED for CT equipment.

The primary energy calculated for the use/maintenance phase is based on 60 patients per day; 20 second scan time, and 10 years' usage, (Siemens).

CED values have been calculated for various CT equipment categories (and with various use scenarios), with slightly different primary energy values, although the overall result is the same for all – the use/maintenance phase consumes far more primary energy than the other phases, followed by the manufacturing/delivery phase while the end of life phase contributes with energy.

One chemical substance to which attention has been paid and whose use has been reduced is Gadolinium Oxide. This is used in the production of CT detector ceramics.

Lead is another substance that is a candidate for substitution. Although it is necessary for radiation-shield purposes, the amount of lead can nevertheless be reduced, fully by balancing weight and partly as radiation shield.

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CT equipment weighs approximately between 2 000 and 5 000 kg; most of it consists of ferrous alloys, steels, 97-98% of which can be physically recycled and 2-3% energetically recycled. The X-ray tube assemblies can be reused, and a tube may comprise up to 40% of reused parts (Siemens).

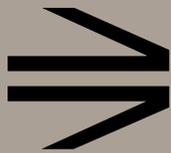
### Cyclotrons

No LCA-related data were found. Company information on the internet indicated that investments are being made in high-efficiency low-energy equipment, which suggests that this is an important area of product improvement.

### Dialysis

An article in a scientific journal concludes that the majority of greenhouse gas emissions in haemodialysis equipment derive from the medical equipment (37%), energy use (21%), and patient travel (20%) sectors. In this case, medical equipment is defined as consumables only, and the footprint is the machine's energy use. The result of the study shows a carbon footprint of 3.8 ton CO<sub>2</sub> equivalents per patient per year for haemodialysis (in a medical setting with treatments three times a week). More frequent treatments often increase the footprint to a greater extent than the duration of treatments. The boundary settings include the medical electrical equipment, but consider it to be part of a treatment regime rather considering the carbon footprint of the medical electrical equipment itself. The production and end-of-life treatment of the electrical equipment also seems not to have been studied. It is therefore difficult to conclude from the article, which part of the equipment's life-cycle has the most significant environmental impact, although it may be assumed that energy usage in the use phase is a significant environmental aspect, as well as the usage of consumables (Connor, 2011).

Another article focuses on the water consumption of dialysis equipment, emphasizing the need for a reduction. Approximately 500 litres per patient (i.e. per four-hour treatment) is consumed. This may be assumed to be a significant environmental aspect for dialysis equipment (Agar, 2010).



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*Figure 6: Dialysis equipment.*

#### Diathermy equipment

No LCA-related data were found.

#### ECG equipment

No LCA-related data were found.

#### Endoscopy equipment

No LCA-related data were found.

#### General information for MRI, CT and X-ray

LCA-related information was found regarding MRI, CT and X-ray equipment. The available information is in accordance with IPP, an integrated product policy, taking into consideration the whole lifecycle of a product. Lifecycle is divided into four phases:

1. Specifications/product design – in this phase design can take into consideration materials used and optimise energy consumption
2. Manufacturing (including Transport) – environmental aspects include, for example, materials, energy and water consumption, waste as well as various emissions. Environmental management can eliminate or minimise these environmental impacts.
3. Use – for healthcare EEE this is a lifecycle phase with large environmental impact due to its energy consumption. This can be minimised at the design

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phase and customers can also be provided with information on how to operate the equipment environmentally.

4. End-of-life/recycling –healthcare systems can be refurbished, components can be reused etc.

Environmental aspects include, for example, environmental protection, resource implementation, energy consumption and disposal. Lifecycle assessments show that the environmental effects of the medical electrical products mentioned above are most significant during their usage.

The following environmental aspects have been identified as significant:

- Materials for production
- Energy consumption
- Hazardous materials
- Radiation exposure
- Emissions
- Waste
- Noise

(Siemens)

Several available environmental product declarations describe the environmental aspects.

Energy consumption has been identified as the most significant environmental aspect; this is why the cumulative energy demand (CED) method is used to determine medical equipment's energy requirements and ways to reduce them. The cumulative energy demand is the total primary energy<sup>4</sup> necessary to produce, use and dispose of a device (including transportation). This approach addresses the entire product lifecycle, from materials and production to operation and recycling. CED is the total amount of primary energy that is needed to produce, use and dispose of a medical device (including all transportation).

The CED approach can therefore be used to calculate total energy demand for each device and a device's resulting environmental impact. For example, if the main energy source is known (which in medical devices is electric power) its contribution to climate change can be estimated.

Data has been provided showing the material-specific energy demand values for 75 categories of materials that are typically used to make medical devices. These values define how much energy is consumed in the provision of an industrial material such as sheet steel — taking into account the entire value chain, from mining the ore to the finished material. Since healthcare EEE

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<sup>4</sup> Primary energy is the energy contained in natural resources prior to undergoing any man-made conversions (e.g. oil, solar).

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factories generally simply assemble components and manufacture few parts in-house, CED values have also been determined for a list of standard components, such as fans, computers, monitors, and keyboards. By putting together all these pieces of the puzzle, the total energy required to provide the materials that make up a product can ultimately be calculated. This has been done for MRI, CT and X-ray equipment (Siemens).

According to the CED method, manufacturing has a low environmental impact compared with the use phase. But in addition to energy consumption, other environmental aspects have been identified at factories:

- Water consumption
- Chemical use
- Generation of waste
- Substances in discharge water
- Emissions to air

SO<sub>2</sub> emissions contribute to acidification of air and water. CO<sub>2</sub> emissions contribute to climate change (Siemens).

Equipment consists of mostly steel and other metals with high recyclability, 93-98%; there are also numerous equipment refurbishment possibilities..

Chemical content was described as an environmental aspect and beryllium and gadolinium oxide have been identified as critical substances which should be phased out or minimised in equipment, in addition to the chemicals listed in regulations such as REACH and RoHS.

Packaging is described but not considered as a significant environmental aspect, as packaging weight is low (less than 3 kg) and contains mostly recyclable steel and wood.

According to the CED method, transport has a low environmental impact compared with the use phase (Siemens).

### Infusion pumps

No LCAs for infusion pumps, have yet been identified. However, an Eco-design preparatory study has been carried out for circulators and electric pumps. These studies do not relate to infusion pumps, but the results of the LCAs could be comparable with infusion pumps since these contain the same type of electronics and have comparable mechanisms. Infusion pumps could therefore be assumed to have results, in terms of life-cycle environmental impacts, that are similar to the pumps included in the studies.

The Environmental Impact analysis conducted using the EC MEEuP model in these studies shows that in all cases it is the use phase that represents the lion's share: improving the energy performance of products is therefore key to reducing their lifetime environmental impact (AEA Energy & Environment, 2008).

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### Linear accelerators

No LCA-related data were found. Company information on the internet indicates that investments are being made in low-energy linear accelerator platforms, which suggest this is an important area of product improvement.

### Medical lighting

One LCA document was obtained on medical lighting, describing individual medical lighting equipment. The LCA document is based on the principles of ISO 14020 which relates the general principles of environmental declaration, in the ISO TR 14025 technical report relating to type III environmental declarations and the IEC PAS 62545, relating to environmental information on electrical and electronic products.

The functional unit is set to “Lighting a surgical space by decreasing shadow - at 87 000 lux -, and supporting two screens, 10 hours a day for 10 years”.

The LCA study was conducted for the following life-cycle stages:

- Extraction of raw materials,
- Manufacturing (including transportation of materials from suppliers to assembly plants),
- Distribution (including packaging and transportation to the customer),
- Use (energy consumption)
- End of life

The LCA document shows that the major contributions to the life-cycle impact originate from the manufacturing phase and the use phase, energy consumption being the most significant environmental aspect (Maquet, 2009).

Even though the above LCA information only includes the example of one category of medical lighting equipment, the result could be compared with medical lighting in general since this contains the same type of electronics. It could therefore be assumed that medical lighting in general would have similar results in terms of life-cycle environmental impacts as the individual items of medical lighting equipment provided in the LCA document.

### Medical freezers and refrigerators

No LCAs have yet been identified for medical refrigerators and freezers. However, an Eco-design preparatory study has been made for commercial refrigerators and freezers. Even though this study does not include medical refrigerators and freezers, the results of the LCA could be comparable to those of medical refrigerators and freezers since these contain the same type of electronics. It could therefore be assumed that medical refrigerators and freezers would have similar results in terms of life-cycle environmental impacts as the commercial refrigerators and freezers included in the study. This study's

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LCA shows that the use phase and the production material/ component production during the manufacturing phase are the two phases with the largest environmental impacts. Almost 100% of the electricity used in the lifecycle of this equipment is related to its use phase (Mudgal, 2010). The type of refrigerant used in the equipment can also be an important environmental aspect, since it can have high GWP (Global Warming Potential). This is noted by a company in their eco-design efforts (BiotechSweden). Under regulations on ozone-depleting substances refrigerants with high ODP (Ozone Depletion Potential) are restricted (European Parliament and the Council of the European Union, 2009-09-16).

#### Monitoring equipment and IT

Personal computers and computer monitors were included in the Eco-design preparatory study of IT equipment, however, IT workstations and servers were not included.

Even though this study does not include medical IT, the results of the LCA may be comparable with those of medical IT since these contain the same type of electronics; it could therefore be assumed that medical IT would have similar results in terms of life-cycle environmental impacts as the IT equipment included in the study.

The results of the LCA in this preparatory Eco-design study show that energy consumption in the use phase is the most significant environmental aspect. The production phase has the second largest environmental impact.

The Eco-design study also shows that the environmental impacts are reduced when LCDs instead of CRTs are used, except for persistent organic pollutants, which show a small increase. It also shows that the impacts are reduced when laptops instead of desktops are used in offices. However, laptops have a shorter use phase than desktops and a more recurrent service scheme (IVF Industrial Research and Development Corporation, 2007-08).

A life-cycle assessment of a computer workstation shows that most energy usage over a workstation's life-cycle results from the operation of the monitor during the use stage of its life-cycle. This is based on life-cycle inventory data for various components such as semiconductors, semiconductor packaging, printed circuit boards, computer assemblies and display monitors. The source of this LCA is however unclear. It could be assumed that energy use during the use phase is the most significant environmental aspect for IT workstations and possibly monitoring equipment as well (Rosselot).

A LCA of two servers was found, which had been carried out on the international standards ISO 14040 and ISO 14044. The LCA shows that the energy consumption in the use phase is the most significant environmental aspect. See figure below (Fujitsu, 2010).

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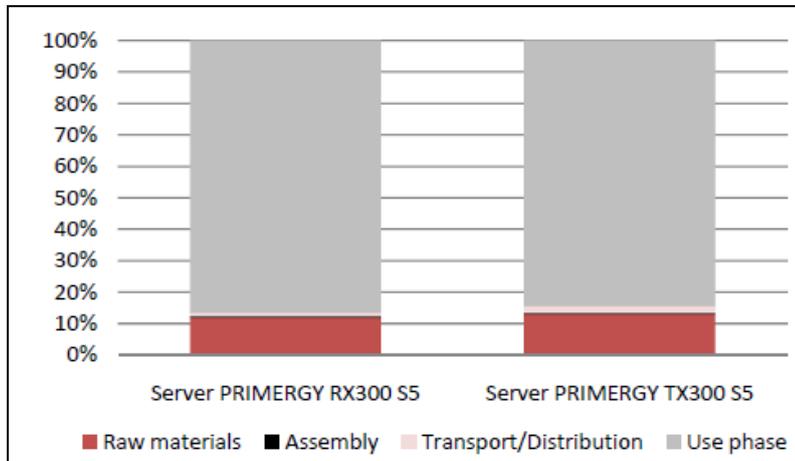


Figure 7: Respective share of the total carbon footprint for two servers.

## MRI

See also information under heading *General information for MRI, CT and X-ray*.

For MRI, material provision amounts to 4 % of the total energy — taking into account the complete life cycle. There is however room for improvement. Forty-five percent of the eight-ton mass of an MRI system consists of various iron alloys and steels, while about 34 % is nonferrous metals and alloys. When considered in the CED context, nonferrous metals such as aluminium and copper account for substantially more energy usage than ferrous metals. Aluminium could be replaced by steel wherever possible to reduce the energy consumption associated with materials supply. Such a switch would also have to be accompanied by design changes to avoid a substantial increase in gross weight.

About 10 % of the total energy demand of the lifecycle is accounted for by the manufacturing phase.

Lifecycle analyses conducted using the CED method show that the use/maintenance phase is the most significant phase as regards energy consumption with its energy consumption being 4-8 times higher than the next phase, production/delivery (calculated over a ten-year period of use). Important factors for a device's energy consumption are heat emissions, cooling needs and power consumption. Within the production/delivery phase, the example of an MRI shows that 37 % derives from the component production and 35 % from delivery. Within the use/maintenance phase, the example of an MRI shows that 62 % derives from scanning and 38 % from pre-scan warm-up or system shutdown. The material supply consumes even less, approximately 70 % less than production/delivery. End-of-life contributes energy rather than using it, as equipment has a high degree of recyclability (Siemens).



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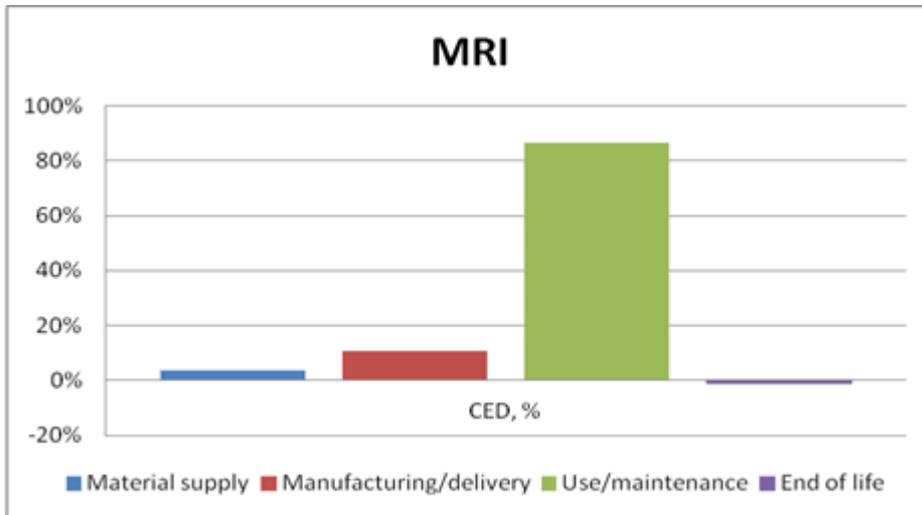


Figure 8: Example of CED values for various life-cycle phases for an MRI.

CED values have been calculated for various MRIs, with slightly different primary energy values, though the overall result is the same – the use/maintenance phase consumes far more primary energy than the other phases, followed by the manufacturing/delivery phase while the end of life phase contributes energy.

The conclusion is that energy consumption in the use/maintenance phase is the most significant environmental aspect. The energy consumption in the production/delivery phase is the second most significant.

MRI equipment can be designed to avoid helium loss. It is only during cold head maintenance that minor helium loss may not completely be avoidable. This allows an increase in refill intervals and thus savings of approximately 700-1300 litres of liquid helium per year. Helium is extracted from natural gas which makes it a scarce resource. To achieve its cooling performance, it must be liquefied, a process that uses a large quantity of energy.

Due to the cooling requirements of its superconducting magnet, an MRI needs a power source that does not warm up. This means that air transportation must be used; according to the CED method, nearly as much energy is consumed during transport to the customer as the manufacture of components (approximately a third of the total energy used in production). But maritime transport can be sufficiently rapid, at least in the case of shorter distances. The coastal route requires just one sixtieth of the energy of air transport.

MRI equipment weighs approximately 6000-8000 kg (including cabinets, workplace equipment and cabling); most of it consists of ferrous alloys, steels; 93% can be materially recycled and 7% energetically recycled (Siemens).

Patient warming systems

No LCA-related data were found.

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### Surgical lasers

No LCA-related data were found. A scientific journal indicates that interest in low-power laser apparatus has grown; it might therefore be assumed that energy consumption is an important factor for this group of medical equipment (Minaev, 2005).

### Ultrasound and Medical imaging equipment

COCIR has written a preparatory study for an Eco-design self-regulatory initiative regarding medical imaging equipment. Medical imaging equipment includes:

- Computer Tomography (CT),
- Ultrasound,
- X-Ray,
- Magnetic Resonance Imaging (MRI),
- Nuclear Medicine (PET/PET CT)

In the COCIR methodology for the Self-Regulatory Initiative, a step-wise process will be implemented in which each modality will be phased in the process year by year. The initiative was started in 2009, with Ultrasound as the first modality. The COCIR study concludes that life-cycle assessment data indicate that, on average, energy consumption during the use phase accounts for about 83% of the total life-cycle environmental impact of ultrasound products where the “use phase” is defined as the time during which the equipment is in use by the customer (the total period from when they receive the equipment to the time that they dispose of it).

The life-cycle assessment of ultrasound equipment was an Easy-LCA based on LIME, a science-based impact assessment which shows a final result as a single score. It considers various phases of the life cycle:

- Materials provision/component production,
- Manufacturing,
- Distribution,
- Use,
- Waste collection and treatment,
- Recycling

The following figure shows the result of a representative LCA performed for an ultrasound product. Another ultrasound product showed similar results, with 86% of the total energy consumption in the life-cycle consisting of energy consumption in the use phase.



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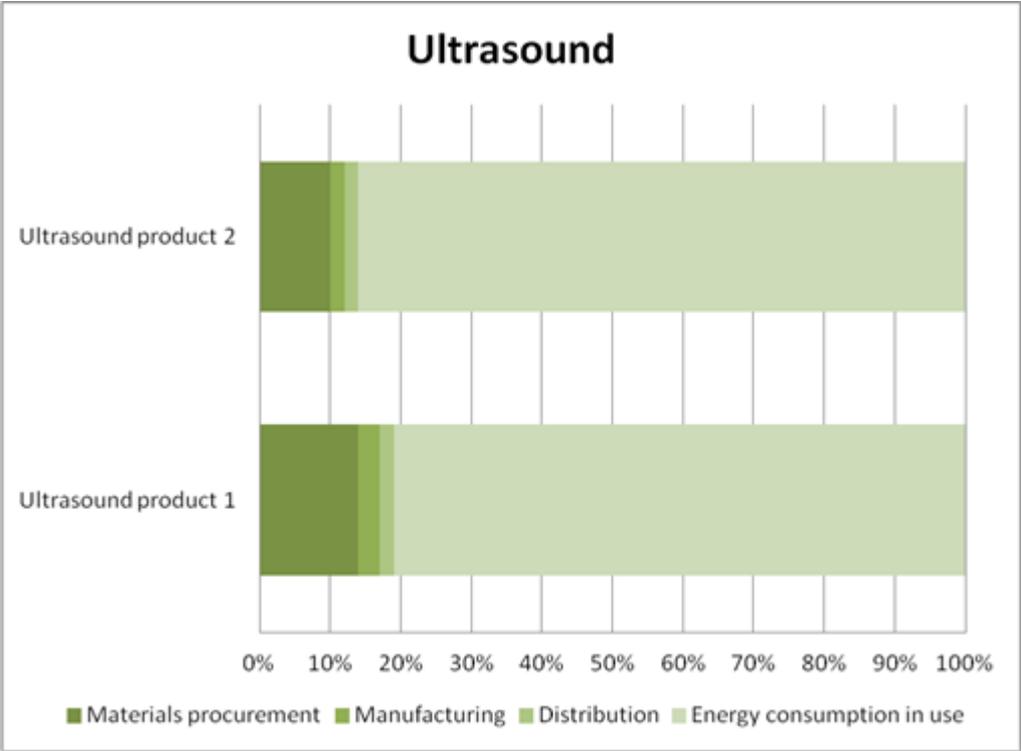


Figure 9: Percentage of total life-cycle environmental impact (LIME) arising from various stages in the life-cycle of an ultrasound product

On average, energy consumption during the use phase accounts for 83% of the total energy consumption in the life-cycle of ultrasound products, and materials procurement accounts for 12%. Adding applied gel and cleaning paper usage to the LCA, the impact of the gel and paper to the total life-cycle impact could be as much as 20%, i.e. considerable<sup>5</sup>.

In addition to the LCA, environmental parameters listed according to the Eco-design Directive were used to evaluate the potential for improving the environmental aspects of ultrasound products. This assessment confirms that the most significant environmental aspects for ultrasound equipment are (COCIR, 2009-10-19):

- Energy consumption during the use phase
- Materials procurement

X-ray

See also information under heading *General information for MRI, CT and X-ray.*

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<sup>5</sup> Calculation is based on: 15 g gel consisting of 86% tap water, 7% propylene glycol, 6% glycerine, 0.55% carboxymethylene, 0.002% FD&C Blue Dye#1; 20 times/day, 7 days a week, 7 years long (calculated with the Eco Indicator 99 impact assessment method)

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The CED method for X-ray equipment shows, as in the case of MRI, that the use phase has the highest energy consumption, followed by the production and transportation phase. See figure below as an example. With an appropriate end of life treatment it is possible to return 27 MWh in the form of secondary raw materials or thermal energy to the economic cycle.

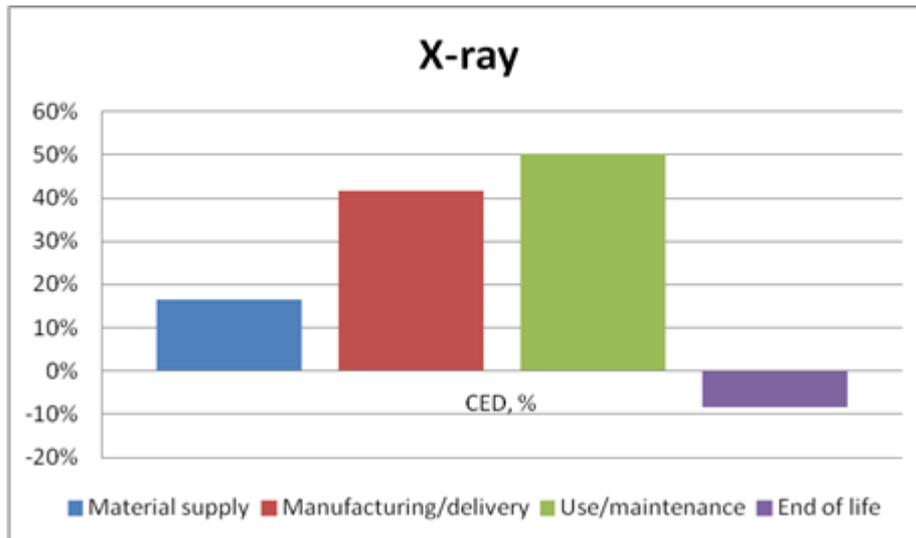


Figure 10: Example of CED values for various life-cycle phases of X-ray equipment.

An example of the substitution of hazardous chemicals is the elimination of use of beryllium in X-ray tube manufacturing. Beryllium is toxic for organic tissue.

One possibility for X-ray equipment is to reuse x-ray tube assemblies. On average, approximately 50% of the weight of one x-ray tube assembly can be recovered and reused. Under optimal conditions up to 40% of a tube assembly may consist of reused parts.

Most of the materials used to produce X-ray equipment are recyclable. For example, 96% of material (by weight) and 4% of the energy value can be recycled (Siemens).

#### 6.4 CONCLUSIONS

As can be seen from Table 3, energy consumption during the use phase is the predominant most significant environmental aspect for all selected healthcare EEE, leading to environmental impacts such as global warming and acidification. Another significant environmental aspect is energy consumption and use of resources related to component and material provision during the manufacturing phase. For certain healthcare EEE, which differ slightly from other healthcare EEE, other environmental aspects are also of importance. This concerns medical freezers which use refrigerants with high global warming potential. Moreover, disinfectant and dialysis equipment use water during the use phase, which are also significant environmental aspects, in addition to their energy usage. Consumables expended in the use phase are significant

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environmental aspects concerning An/Iva equipment, dialysis equipment as well as diathermy and ECG equipment. However, consumables such as masks, tubes, containers, electrodes, etc. are not part of the scope of this technical report. Neither are use of detergents or chemicals relevant for disinfectant and dialysis equipment—these will also be handled in phase 2 as they are also considered consumables. Environmental aspects such as helium use (applicable for MRI), chemical substances or gas usage will be further discussed with stakeholders and experts during the criteria development process. As for chemical substances, these are seldom included in LCA and chemicals risks are not assessed throughout the life cycle. This means that the analysis made on the most important environmental aspects might be misleading. In light of the fact that the UN chemicals agreement is not on track to meet the goal on sound management of chemicals by 2020 it is important not to disregard the chemical aspect. In the UNEP report “Global Chemicals Management” from 2012, procurement is earmarked as an economic instrument for sound management of chemicals. With this in mind it is suggested that this environmental aspect should be treated further within the stakeholder group and be included for consideration in the development of GPP criteria.

Aspects such as noise and radiation are not part of the scope.

#### 6.4.1 SUMMARY

The following environmental aspects will be discussed during the criteria development process:

- Energy usage during the use phase
- Water usage during the use phase in dialysis and disinfectant equipment
- Materials and component provision during the manufacturing phase
- Use of hazardous chemicals (i.e. content of hazardous chemicals in equipment)
- Gas usage during the use phase in anaesthesia equipment
- Use of refrigerants in medical freezers (i.e. content of high GWP refrigerants)

Social aspects will also be considered, see *Chapter 7*.

## 7 SOCIAL ASPECTS

### 7.1 CORPORATE SOCIAL RESPONSIBILITY (CSR)

Corporate Social Responsibility (CSR) refers to companies voluntarily making efforts to integrate social and environmental considerations into their business.

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According to the European Commission, the term means “a concept where companies integrate social and environmental considerations into their business and interaction with their stakeholders.”

According to the international standard ISO 26000 (International standard organisation, 2010), social responsibility is not merely a “neutralising” action applied at the end of production/distribution to fix what has been generated or displaced. Rather, it is a proactive mind-set that should be incorporated across all levels of planning, execution and stakeholder interaction.

ISO 26000 acknowledges that applying a lens of social responsibility can be complex. The standard makes it clear, however, that “a situation’s complexity should not be used as an excuse for inaction,” and that companies should proceed in good faith, applying the seven principles of socially responsible behaviour as outlined in the standard: accountability, transparency, ethical behaviour, respect for stakeholder interests, respect for the rule of law, respect for international norms of behaviour and respect for human rights.

## 7.2 INTERNATIONAL FRAMEWORK

### 7.2.1 INTERNATIONAL LABOUR ORGANISATION (ILO)

The ILO (Int) is the international organisation responsible for drawing up and overseeing international labour standards. The ILO is a convention-based organisation with over 180 conventions. In 1998, the ILO adopted a declaration on basic principles and rights. These conventions are referred to as the ILO core conventions:

- Forced Labour Convention (ILO 29)
- Freedom of Association and Protection of the Right to Organise Convention (ILO 87)
- Right to Organise and Collective Bargaining Convention (ILO 98)
- Equal Remuneration Convention (ILO 100)
- Abolition of Forced Labour Convention (ILO 105)
- Discrimination (Employment and Occupation) Convention (ILO 111)
- Minimum Age Convention (ILO 138)
- Worst Forms of Child Labour Convention (ILO 182)

### 7.2.2 OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES

The OECD Guidelines (OECD) are recommendations from governments to multinational enterprises operating in or from adhering countries. They provide voluntary principles and standards for responsible business conduct in areas such as employment and industrial relations, human rights, environment,

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information disclosure, combating bribery, consumer interests, science and technology, competition and taxation.

### 7.2.3 THE UN “PROTECT, RESPECT AND REMEDY” FRAMEWORK FOR BUSINESS AND HUMAN RIGHTS

The UN Framework “Protect, Respect and Remedy” has been developed to declare companies responsible for the protection and framing of human rights. Companies cannot be attributed the same responsibility to promote human rights. However, they have a responsibility to respect these in their business and take action, and not participate in violating human rights.

### 7.2.4 GLOBAL COMPACT

The Global Compact (Glo) (United Nations Global Compact) is an UN-initiative, which contains 10 principles for companies’ social responsibility. The principles are based on international conventions on human rights, working conditions, environment and anti-corruption.

## 7.3 SOCIAL RESPONSIBILITY IN PUBLIC PROCUREMENT

The procurement directives regulate the possibility to contemplate social considerations in public procurement (Dir1). According to Directive 2004/18/EC, article 26, contracting authorities may lay down special conditions relating to the performance of a contract, provided that these are compatible with EU law and are indicated in the contract notice or specifications. The conditions governing the performance of a contract may, in particular, concern social and environmental considerations.

In the preamble, Directive 2004/18/EC states that the contract performance conditions are compatible with the Directive, provided that they are not directly or indirectly discriminatory and are indicated in the contract notice or contract documents. They may aim to make sure that the procured products are being produced in a way that comply with the provisions of the basic International Labour Organisation (ILO) Conventions, assuming that such provisions have not been enacted into national law.

The European Commission has also published guidelines on socially responsible public procurement, “Buying Social - A Guide to Taking Account of Social Considerations in Public Procurement” (European Commission, 2011). The non-binding EC document gives guidance on how to include social considerations into public procurement decisions and tendering in the EU legal framework.

## 7.4 SOCIAL RESPONSIBILITY IN HEALTHCARE

Social responsibility in the healthcare sector has been observed in reports during the last few years. These reports have shown that there is a lack of

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decent working conditions in the manufacturing of the products which the European public sector procure to provide needs within the healthcare sector.

The labour problems concern the use of dangerous equipment, health and safety issues, low wages, long working hours, the use of child labour and no free unions. The lack of control in the supply chain and unacceptable working conditions has been clearly shown.

Since these problems have been observed, some initiatives have commenced in the public sector in different countries in Europe such as England, Sweden and Norway.

#### 7.4.1 FAIR MEDICAL CARE

In England, the Medical Fair and Ethical Trade Group was instigated in 2007 to facilitate fair and ethical trade in the production and supply of medical supplies. Medical Fair and Ethical Trade Group within the British Medical Association, BMA (Ethical Trading Initiative), started a project together with Ethical Trading Initiative (ETI) (Ethical Trading Initiative).

In May 2011, a guidance for ethical trade in the health sector was published, "Ethical procurement for Health" (Ethical Trading Initiative). One initiative for ethical trade with medical supply, Fair Medical Care, has also been started (Fair medical trade).

#### 7.4.2 SWEDISH COUNTY COUNCILS

The three biggest county councils in Sweden: Stockholm County Council, Region Västra Götaland and Region Skåne, started a common project for socially responsible public procurement in 2007. They adopted a common Code of Conduct and started to set social criteria in some prioritised product groups. This can be seen as a reaction to the reporting from SwedWatch in 2007 "The Dark side of Healthcare" (Swedwatch, 2007). From the outset, these county councils have been in a leading position in socially responsible public procurement in Europe.

In 2010, the project became permanent, and all Swedish county councils take part in this work. Since the beginning, the product groups have increased in number and they are focusing on making common follow ups to be able to learn from each other and exchange experiences.

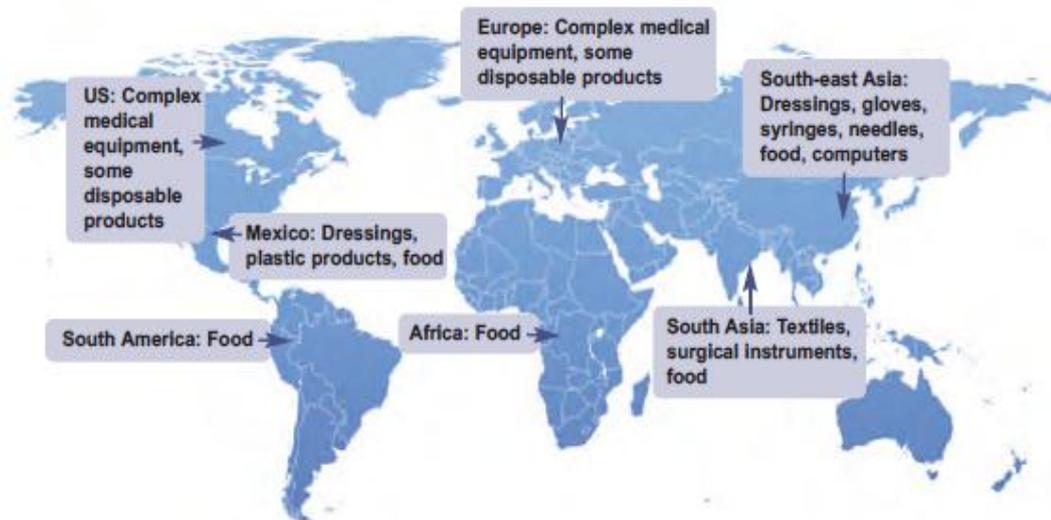
#### 7.4.3 THE HEALTH REGIONS IN NORWAY

The Norwegian healthcare region, Helse Sør-Øst, has worked with ethical trade in their procurement since a few of years back. Helse Sør-Øst is also a member of the Ethical trading Initiative (IEH) in Norway (Ethical Trading Initiative). Since 2011, all Norwegian health regions have started a common project for socially responsible procurements in the healthcare sector, which is being carried out together with the IEH (Initiativ for etisk handel).

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## 7.5 THE MEDICAL EQUIPMENT SUPPLY CHAIN

Medical equipment for the European healthcare sector is manufactured all over the world. A general conclusion is that high-tech medical equipment is mainly being manufactured in the US and Europe, while low-tech products are being manufactured in low cost countries.



*Figure 11: Manufacturing of medical equipment for the healthcare sector: (BMA Medical Fair and Ethical Trade Group, Ethical Trading Initiative [ETI] and Department of health)*

As seen above, complex medical equipment, such as healthcare EEE, mainly takes place in the US and Europe, although some production takes place in low-cost countries. However, healthcare EEE are products which contain many different components and the supply chain can be long, with many different sub-suppliers. The manufacturing of electronics and monitors for example is often located in Asia.

The manufacturing of low-tech products, such as medical supplies, has been moved to low cost countries, in order to make production as cheap as possible. Production and trade with these goods have become an important source of revenue for these countries. However, during the last few years, unacceptable working conditions in the production of medical supplies to the healthcare sector have been reported.

### 7.5.1 SOCIAL RISKS IN THE HEALTHCARE EEE SUPPLY CHAIN

High-tech medical equipment, such as medical electrical equipment, are complex products which set out special demands for manufacturing. For example, employees have to be competent and well educated, which also means that they are very valuable to the company. These products are also regulated in a setting of very detailed legislation and standards. The social risks are therefore smaller in this sector compared to low-tech products.

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However, the fact that healthcare EEE are high-tech products does not mean there is no social risk at all. Generally, the social risks are higher further down the supply chain. Production by sub suppliers might therefore be a different issue. For example, the social risks are higher for components within healthcare EEE that are being produced in low cost countries. It is therefore important for suppliers of medical equipment to the public sector to integrate social aspects into their contracts with their suppliers and sub-suppliers. Social aspects will thus be addressed down the supply chain where the risks might be higher.

The SRPP (Socially Responsible Public Procurement) criteria should focus on including social aspects. Even if the risks may be lower compared to products which are so called low-tech products, it is important that social criteria be a part of the contracts between suppliers and sub-suppliers. The risks are higher down the supply chain. The criteria should contain fundamental human rights with references to ILO core conventions.

The supplier must be able to ensure that their work process does not violate human rights in the production of the products being delivered within the contract to the contracting authority. The supplier should at the very least:

- Have a person responsible for social responsibility in the supply chain
- Have knowledge about where the products being delivered are being produced
- Have conducted a risk analysis in the supply chain
- Set social requirement on their suppliers (with references to the ILO core conventions), in a Code of Conduct or similar

#### 7.5.2 FOLLOWING UP SOCIAL CRITERIA

Social criteria must be followed up. The contracting authorities have a responsibility to make sure that their suppliers are followed up in a way that can guarantee that they follow their obligations. Otherwise, the risk could also be that the suppliers are not being equally treated, and the contracting authority is also risking violating EU principles.

It must be clear and transparent, both for the contracting authority and the supplier, how the follow-up is going to be fulfilled. The contracting authorities can use a supplier self-assessment template for this.

## 8 LIFE-CYCLE COSTING

LCC analyses consider the total cost of a product during its entire life cycle. This includes taking operating and maintenance costs as well as the initial investment including installation costs into account. Other costs which may be important in this context are energy consumption or other relevant

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consumption, such as gas or water, disposal costs/rest value and costs for reinvestment.

The initial investment forms only one part of the total costs involved in a product and by employing a longer term perspective, investments that appear costly at the moment of purchase may pay off in the long term through low operating and maintenance costs. Higher energy prices may also add to future costs.

The Swedish Environmental Management Council includes LCC when developing criteria, if this is considered relevant. In order to help the procurer use LCC, a guide is attached to the LCC-criteria as well as a calculation tool. The calculation tool can be used in both the needs-analysis and tender evaluation to clarify the total cost for a product during the period of use.

Within the area of Medical devices LCC is widely used. Several calculation tools are available on the Internet, such as a British tool from the NHS, the Purchasing and Supply Agency.

According to the NHS energy costs can represent a significant proportion of medical device operating costs. The electricity consumption of medical devices also varies significantly across the wide range of equipment. Devices used in radiography tend to use much more electricity than filtration equipment or infusion pumps but the less energy intensive devices are generally procured in much higher numbers, and the aggregated energy use may be significant.

LCC can be used in different ways and it is therefore important to stress the identification of relevant parameters to include. Calculation tools available differ markedly as to the level of specification and some include a minimum number of parameters such as acquisition cost and electricity costs while some contain parameters for initial investment, life time of the machine, rest value, maintenance and repair and running supplies including electricity and gas but also for disposables. Others contain specified service costs, defined in the tool as well as costs for education and spare parts. Consequently, different calculation tools contain different parameters, depending on the need in the specific procurement. If LCC is to be used in the tender document it needs to clearly describe the parameters which must be included in the calculation and the documentation of the measurement methods to be applied so it is clearly evident which information the tenderer must provide. This is especially important for energy consumption where a specified calculation method must be attached in order to obtain comparable numbers to use in the LCC.

Medical devices contain several products and it is important to examine whether the same parameters can be used for the different products and if it is possible to use one common general calculation tool that comprises all the parameters. Otherwise, separate tools must be made combined with several different specified LCC-criteria.

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## 8.1 THE NHS TOOL

The NHS British Purchasing and Supply Agency, has developed a tool for energy efficiency assessment for electrical medical devices. The tool can be used to compare the energy efficiency and whole-life energy costs of several similar products or models at the tender evaluation stage. It can also be used to assess the energy or carbon emissions from the products.

The tool follows a stepwise approach consisting of five stages:

1. **Significance of energy use.** The first step is to determine whether the energy consumption is significant; otherwise, a full assessment might not be warranted.
2. **Unit energy cost.** If energy consumption is significant the unit energy costs, i.e. local cost per kilowatt-hour, should be established.
3. **Operating assumptions.** At this stage key operating assumptions, such as how long the device will be switched off, on stand-by, or operational, taking into account different modes of operation, are determined.
4. **Energy consumption.** The energy consumption for the different operational modes identified in stage 3 is determined, using information provided by suppliers.
5. **Whole life energy cost.** The tool provides data tables and graphical outputs of the expected whole life energy consumption, energy costs and associated carbon emissions using the information determined in the previous stages (NHS Purchasing and Supply Agency, 2009).

## 9 LEGISLATION, STANDARDS AND LABELLING

### 9.1 MEDICAL DEVICES DIRECTIVES

The EU legislative framework governing medical devices includes three directives. These Directives establish specific health and safety requirements for several products that fall within the general category of healthcare products:

- the Medical Devices Directive (93/42/EEC, as amended by Directive 2007/47/EC);
- the Active Implantable Medical Devices Directive (90/385/EEC, as amended by Directive 2007/47/EC); and
- the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Even if these Directives have a clear focus on patient safety, environmental considerations are also made. In Annex I of the Medical Devices Directive, section II: Requirements regarding design and construction, it is stated that “particular attention must be paid to the choice of materials, especially as regards toxicity and, where appropriate, inflammability”. It is also stated that

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“the devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device”.

## 9.2 ROHS

In the RoHS Directive (2002/95/EG) the use of mercury, cadmium, lead, hexavalent chromium and the flame retardants PBB and PBDE in new electric and electronic products released to the market is regulated. The threshold levels are 0.1 weight% for lead, mercury, hexavalent chromium, PBB and PBDE in homogenous material and 0.01 weight% for cadmium in homogenous material. The motives for the RoHS-directive are partly the health and environmental hazard of the substances and partly the fast technology development of electric and electronic products. The products are often replaced before they have reached end of life and new fields of application are steadily introduced. In total, a considerable amount of hazardous substances are used in electric and electronic products. The increasing amount of electric and electronic products also contributes to a large amount of waste.

Principally, it is when the products turn into waste that the substances can become a burden to the environment, especially if the waste is not correctly processed. The content of hazardous substances also makes cost-effective recycling difficult for the products collected.

RoHS will come into force in 2014 for medical devices and in 2016 for medical devices for in vitro-diagnostics.

## 9.3 WEEE

It is important that materials in EEE are correctly taken care of in their end-of-life stage, since they may contain hazardous substances and recycling of materials is ensured. Electric and electronic products contain many hazardous substances. The producer responsibility means that the producer or importer of EEE has the responsibility to label the products, collect the waste and make sure it is reused, recycled or handled in a way that benefits the environment and minimises the environmental impact.

Producer responsibility is regulated in the WEEE-Directive (2002/96/EG). Healthcare EEE are included in the WEEE-Directive.

## 9.4 REACH

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (2006/1907/EG) is the European regulation concerning chemicals. This regulation is founded on the principle that the producers, importers and downstream users are responsible for ensuring that the substances they produce, release to the market or use will not have any harmful health and environmental effects. The regulations are based on the precautionary principle. REACH implies that new substances and those already existing on the market have to be registered, risk evaluated and authorised.

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The REACH-Candidate List (article 59) contains SVHC-substances (substances of very high concern), which means substances with undesired properties such as: carcinogenic, persistent and endocrine disrupting substances. Identification of substances included on the Candidate List is a continuous process; this means that new substances are added gradually. ECHA (the European Chemicals Agency) recommends priority substances from the Candidate List for inclusion in the Authorisation List (Annex XIV). The European Commission takes the decision to include a substance in the Authorisation List by means of a regulatory committee procedure. That substance is still included in the Candidate List.

If an article contains more than 0.1 weight% of a substance included in the Candidate List, the supplier has to provide their customers sufficient information to allow safe use of the article. This information must contain as a minimum the name of the substance. Similar information has to be provided upon request to a consumer within 45 days of receipt of the request.

There are no general exemptions for medical devices from REACH (as occurred before in RoHS). Although when it comes to granting authorisations (Article 60), medical devices are treated differently:

“The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices<sup>1</sup>, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.”

This means that the “use phase” of the medical device must not be included in the granting of authorisation.

## 9.5 THE ECO-DESIGN DIRECTIVE

Within the scope of the eco-design directive (278/2009/EG) there are regulations concerning minimum standards for different product categories where technique is available for increased energy efficiency and lowered energy use.

In total, the minimum standards have a significant effect on reducing energy use. The Eco-design criteria together with the Energy-labelling is estimated to save 1116 TWh in EU by the year 2020, which is approximately 5% of the primary energy.

There are currently no eco-design regulations regarding healthcare EEE, but COCIR is developing targets in a Self Regulatory Initiative for Medical Imaging Equipment (2009). These include:

- MRI
- CT

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- X-ray
- NM
- US

## 9.6 STANDARDS

### 9.6.1 IEC INTERNATIONAL ELECTRO TECHNICAL COMMISSION

The International Electro technical Commission (IEC) is the world's leading organisation that prepares and publishes International Standards for all electrical, electronic and related technologies. IEC standards published by TC 62 and its subcommittees cover safety and performance for specific products, such as diagnostic imaging, radiotherapy, nuclear medicine, radiation dosimeter, electro medicine, anaesthesia, critical care, surgery, artificial respiration and paediatrics.

TC62: Electrical equipment in medical practice

The committee's tasks are to prepare international standards and technical reports concerning the manufacture, installation and application of electrical equipment used in medical practice and their effects on patients, operators and its environment. This also concerns surgery, dentistry and other medical specialism. There are four subcommittees as follows:

Subcommittees:

SC 62A: Common aspects of electrical equipment used in medical practice

SC 62B: Diagnostic imaging equipment

SC 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry

SC 62D: Electromedical equipment

Other identified IEC standards of potential interest for criteria development are:

- IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

There are also a large number of product-specific standards for different types of equipment, including ECG printer, ventilators and x-ray equipment.

- IEC 60601-1-9 Environmentally Conscious Design of Medical Electrical Equipment

The aim of this collateral standard is to improve the environmental impact for the entire range of medical electrical equipment, taking all stages of the product life cycle into account:

- product specification
- design
- manufacturing

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- sales, logistics, installation
- use
- end of life management.

This means protecting the environment and human health from hazardous substances, conserving raw materials and energy, minimizing the generation of waste, as well as minimizing the adverse environmental impact associated with waste. The criteria needed to attain this goal must be integrated into all stages of the medical electrical equipment life-cycle from the specification stage to end of life management. The environmental impact of medical electrical equipment through all life-cycle stages are determined from the medical electrical equipment's environmental aspects defined during the identification of need, product planning and design stages. Environmental protection is one element of the overall risk management process as required by the general standard.

The specific environmental requirements of IEC 60601-1-9 are set out below.

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<b>CLAU E</b>		<b>CLAUSE REQUIREMENTS IN SECTION 4 OF IEC 60601-1-9</b>
4.1		Identify the environmental aspects of the new product design across all of the product's life-cycle stages
4.2		Determine which of these environmental aspects can have significant environmental impact across the product's life-cycle stages. These are identified as significant environmental aspects.
4.3		Gather information during the concept and design stage from suppliers whose products and services are likely to contribute significant environmental aspects to the final product.
4.4		Set targets for the significant environmental aspects to minimise as far as reasonably possible the product's significant environmental impact across all life-cycle stages. The design concept and specification setting stages shall consider novel, emerging or alternative technologies and/or solutions that can reduce the product's significant environmental impact.
4.4		Assess the actual significant aspects of a representative prototype across all life-cycle stages. Any deviations from the targets shall be assessed and documented for consideration in future designs.
4.5.1		Make available information on the type and mass of packaging materials.
4.5.2		Provide instructions in user manuals for minimising the environmental impact of the product during normal use.
4.5.3		Provide information to end-users on correct disposal of the product at end of life, and provide information to waste processing facilities for environmentally responsible management of the waste products

*Table 5: Clause requirements in Section 4 of IEC 60601-1-9*

The compliance assessment checks specified in the standard are based on verifying that procedures are in place and that there is documented evidence of them being followed.

#### 9.6.2 CENELEC STANDARDS IN EU

- CENELEC is the European Committee for Electrotechnical Standardisation and is responsible for standardisation in the electrotechnical engineering field.

#### 9.6.3 ISO STANDARDS

Identified ISO standards of potential interest for criteria development are:

- ISO 14001:2004 — Environmental management systems
- ISO 9001:2008 — Quality management systems

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- ISO 14006:2011 — Environmental management systems — Guidelines for incorporating ecodesign
- ISO 13485:2003 Quality management systems — Requirements for regulatory purposes.
- ISO 14971 Medical Devices — Application of Risk Management to Medical Devices – 2007

## 9.7 ENVIRONMENTAL DECLARATIONS AND LABELLING

### 9.7.1 VOLUNTARY AGREEMENTS

There are several different voluntary (and mandatory) environmental performance labels and declarations. The International Organisation for Standardisation (ISO) has identified three broad types of voluntary labels:

**Type I (ISO 14024)** multiple criteria-based, third party programme that awards a license that authorises the use of environmental labels on products indicating overall environmental preference of a product within a particular product category based on life-cycle considerations

**Type II (ISO 14021)** informative environmental self-declaration claims

**Type III (ISO/TR 14025)** environmental product declaration, EPD, voluntary programmes that provide "quantified environmental data for a product with pre-set categories of parameters based on the ISO 14040 series of standards, but not excluding additional environmental information".

### 9.7.2 ECO-LABELLING

"Eco-labelling" is a voluntary method of environmental performance certification and labelling practiced around the world. An "eco-label" is a label that identifies overall environmental preference of a product or service within a specific product/service category based on life-cycle considerations. In contrast to "green" symbols or claim statements developed by manufacturers and service providers, an eco-label is awarded by an impartial third-party in relation to certain products or services independently determined to meet environmental leadership criteria (IVF Industrial Research and Development Corporation, 2007-08). In Europe there are several national eco-labels and other labelling schemes. Some are described below.

#### The European Eco-label, the Flower

The European Eco-label (Regulation ED No 1980/2000), the Flower, was started in 1992 and can be found throughout the European Union as well as in Norway, Lichtenstein and Iceland. The ecological criteria for the award of the European eco-label are the result of scientific studies and consultation within the European Union Eco-labelling Board (EUEB). Members of this board are: the Competent Bodies of the Member States, representatives of environmental

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NGOs, consumer and industry associations, trade unions and representatives from SMEs and commerce. After the EUEB has proposed criteria for a product group they have to be approved by the Member States and the European Commission before they can be used to award the eco-label to products.

Medical devices are excluded from the European Eco-label (Regulation ED No 1980/2000).

#### TCO Development, TCO label

The TCO label is a global label. The TCO labelling started in 1992 and covers environmental issues, and issues regarding the work environment such as image quality, visual and work load ergonomics, noise, electromagnetic- and chemical emissions.

No medical devices are TCO-labelled.

#### Energy Star

Energy Star is a government-backed symbol for energy efficient products and practices, established by the USA Environment Protection Agency (EPA).

No medical devices are labelled with Energy Star.

#### Nordic Eco labelling: The Swan

The Swan is the official Nordic eco-label, introduced by the Nordic Council of Ministers in 1989. Today there is no healthcare EEE labelled with the Swan.

### 9.8 EMAS AND ISO 14001

The medical equipment industry has established and implemented Environmental Management Systems (e.g. EMAS and ISO 14001). These cover the operation and the processes of the industry (waste management, energy efficiency of the installations, green procurement, recycling etc.) and not the products.

EMAS (Eco Management and Audit Scheme) is the European Commission's environmental management system for evaluation, report and control of an organisation's environmental performance.

### 9.9 MEASURING METHODS

There is a lack of commonly agreed energy performance measurement methods and standards for healthcare EEE across Europe.

However, COCIR is in the process of developing commonly agreed energy performance measuring methods for medical imaging equipment (see chapter 9.5 The Eco-design directive).

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Dialogues with stakeholders both from industry and hospitals indicate that there are good possibilities to include energy consumption measuring methods in the development of GPP criteria.

The prioritised product categories can be divided into two groups: one with more complex equipment and one with less complex equipment. The more complex equipment would need more guidance regarding user modes (for example: on, off, sleep, stand-by, shut-down, start-up), multi-functionality, etc. The energy usage would also be dependent on different types of patient examination or treatment. Usage scenarios would have to be defined by the hospitals.

Energy consumption measuring methods can be developed in accordance with quality/functional standards. An example is ISO 15883-1, the terms, definitions and tests used for disinfectant equipment.

## 10 MARKET DATA

### 10.1 PURPOSE OF MARKET DATA COLLECTION

Market data was intended to be collected in order to:

- Estimate the importance of GPP for medical devices, in particular healthcare EEE, in relation to the total healthcare EEE market in the EU
- Estimate which product groups within healthcare EEE to prioritise

More specific market data regarding environmental performance of the market was intended to be gathered in order to assess what type of GPP criteria would be feasible and what levels should be set for these.

### 10.2 RESULTS OF MARKET DATA GATHERING

#### 10.2.1 ESTIMATION OF THE PUBLIC PROCUREMENT MARKET

The total government expenditure of medical products within the EU was 120 432 million Euros (data from year 2008). It was not possible to collect data on a more detailed level, nor from a more recent year, since data for this was not available.

As we do not have the data for the total medical products market, or any data regarding solely the healthcare EEE, it is difficult to assess the importance of GPP for healthcare EEE. In many parts of Europe, healthcare is tax funded and provided by the government or county councils or other public organisations; therefore, a large number of medical products in these countries are publically procured.



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### 10.2.2 MARKET DATA PER HEALTHCARE EEE PRODUCT CATEGORY

Available market data was scarce, but data from PRODCOM for year 2009 were gathered and compiled, see figures below. Data from PRODCOM for year 2006 is present in the Eco-design report Study for preparing the first Working Plan of the Eco-design Directive, Annex 15 (EPTA, 2007). A problem is that the PRODCOM codes have changed over the years and are difficult to compare. The preliminary evaluation is that the prioritisations made (see chapter 3) match the volumes sufficiently, although some of the prioritised product categories are difficult to assess regardless of whether or not they are included in the PRODCOM codes.

It is difficult to obtain detailed market statistics because of the fact that individual companies are not willing to share this information with other associations/organisations due to confidentiality, and no association has access to market data that would cover the entire market and all of EEE.

Compiled data from PRODCOM 2009:

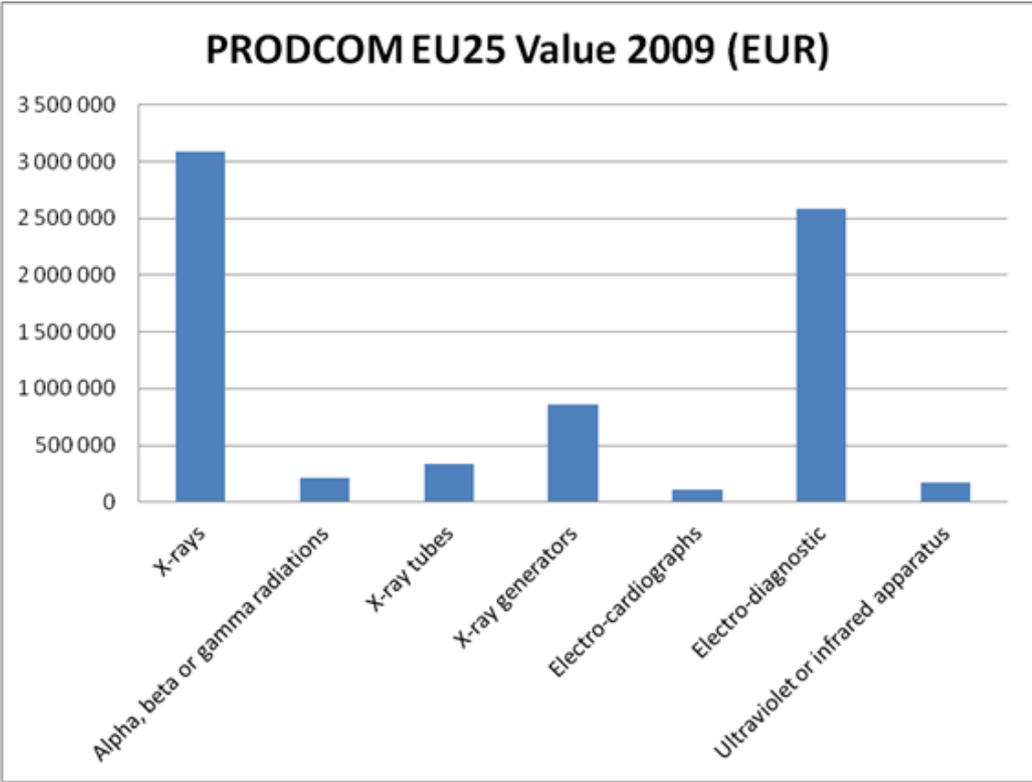


Figure 12: PRODCOM EU25 Value in Euros, year 2009, for healthcare EEE.



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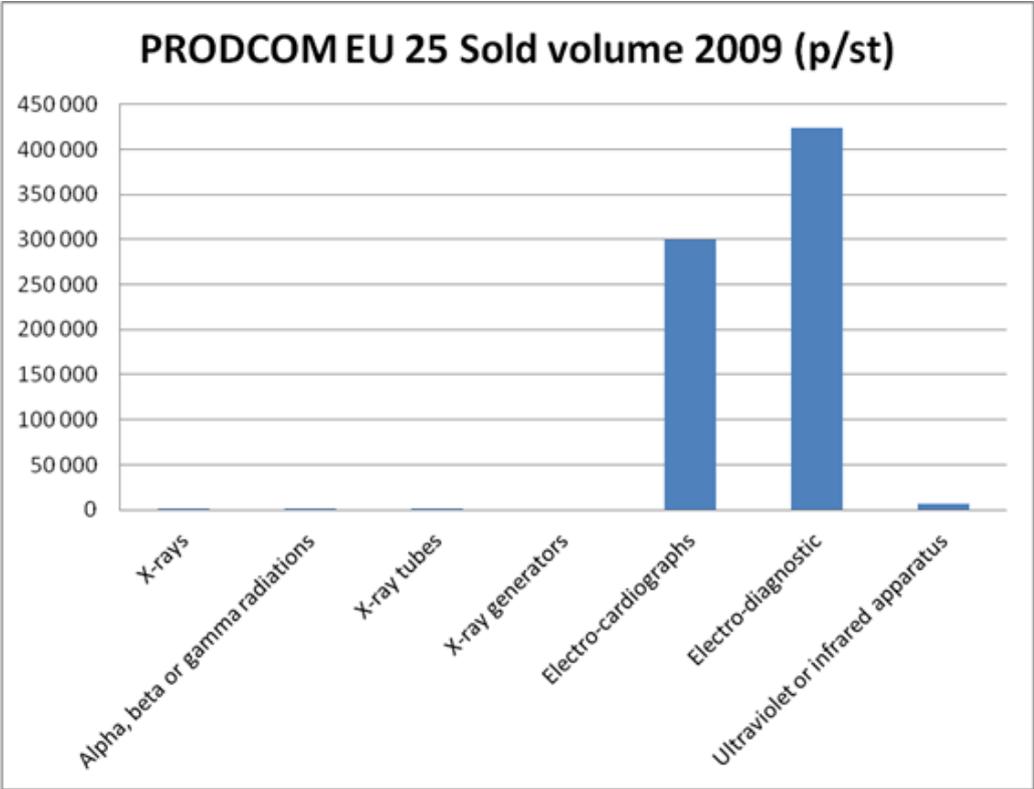


Figure 13: PRODCOM EU25 sold volume (amount – p/st), year 2009, for healthcare EEE.

### 10.3 ENVIRONMENTAL PERFORMANCE OF THE MARKET

No compiled information regarding sustainable products on the market has been found. For example, there is no Eco-labelling for healthcare EEE, and subsequently no statistics regarding market shares that comply with Eco-labelling criteria, such as the Energy star data base. Healthcare EEE is not subject to energy classes, and therefore it is not possible to compile statistics from websites such as Price runner.

The way to gather information and compile this is to send a RFI, Request For Information, to the companies in the healthcare sector producing or selling healthcare EEE. This has been done via COCIR, Eucomed and Swedish Medtech.

COCIR is a European trade association representing members producing or selling radiological, electromedical and/or healthcare IT equipment. Radiological equipment includes medical imaging products such as magnetic resonance imaging (MRI), computed tomography (CT), diagnostic ultrasound equipment, nuclear medicine and radiotherapy equipment. Electromedical products include patient monitoring equipment for use in intensive care units, anaesthetic and respiratory equipment as well as electromedical equipment used in surgical interventions. Examples of healthcare IT are products such as

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Picture Archiving and Communication Systems (PACS) and electronic patient records (EPR).

Eucomed represents members in both national and pan-European trade and product associations as well as medical technology manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and improvement of disease and disability.

Swedish Medtech, the Swedish trade association for medical devices, was targeted to receive a clear picture of the Swedish market.

An additional 66 companies were contacted which were not members of the trade association.

The purpose of the RFI was to generate sufficient replies in order to obtain a picture of the environmental performance of the market, which would serve as guidance in the development of GPP criteria.

The questions in the RFI concern environmental management, standards and labelling, LCA, energy consumption, heat generation, chemicals, water consumption, gas consumption, helium consumption, refrigerants, social/ethical work, recycling/waste management and weight reduction. The RFI can be found in Appendix V.

### 10.3.1 RESULTS FROM RFI

At the beginning of June 2011 SEMCo and Swedish Medtech sent the RFI to approximately 100 companies. The RFI was also sent to 13 companies by COCIR and to the Eucomed member companies by Eucomed. Despite a few reminders the answers were scarce and the due date was therefore postponed. Unfortunately this did not increase the number of answers which in total became ten. To try to gather further market information, it was decided to conduct telephone interviews with key persons at the companies.

Initially the response from the companies to participate in the interviews was positive. Since it was difficult to find someone that could answer all questions in the RFI only three interviews were conducted.

SEMCo decided to interrupt the gathering of market data by RFI and interviews due to lack of time.

SEMCo is very grateful to the companies that made the effort to reply. The information has been useful to the criteria development in a qualitative way, rather than the intended quantitative way. The data will not be compiled in this report, since there is no statistical value because of the small reply frequency.

Because of the lack of statistics on environmental performance and the lack of commonly used energy performance measuring methods, minimum levels regarding energy efficiency were difficult to set in the GPP criteria.

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However, stakeholder and expertise dialogues, as well as meeting frequency, were intensified, in order to extract the gathered extensive expertise and concentrate this into criteria for green public procurement.

## 11 CRITERIA DEVELOPMENT PROCESS

This chapter gives a brief summary on how the criteria development has proceeded within the stakeholder/expertise groups and what conclusions the group came to which lead to the suggested draft criteria (the draft criteria can be seen in the separate draft criteria document).

### 11.1 CRITERIA DEVELOPMENT STAKEHOLDER INVOLVEMENT

The different stakeholders and expertise have been and are continuously being involved throughout the process (see Figure below). A preparatory meeting group with meetings in Sweden has been supporting SEMCo with detailed expertise regarding all four sustainable aspect areas (mentioned below). European expertise has also been involved, commenting on draft versions of the criteria, contributing with their knowledge and experience. They have also participated in an ad hoc working group meeting in Brussels, open to all stakeholders.

Currently, the technical report and draft criteria are published for public open consultation, in order to receive as much input as possible before the second ad hoc working group meeting in Brussels, open to all stakeholders.

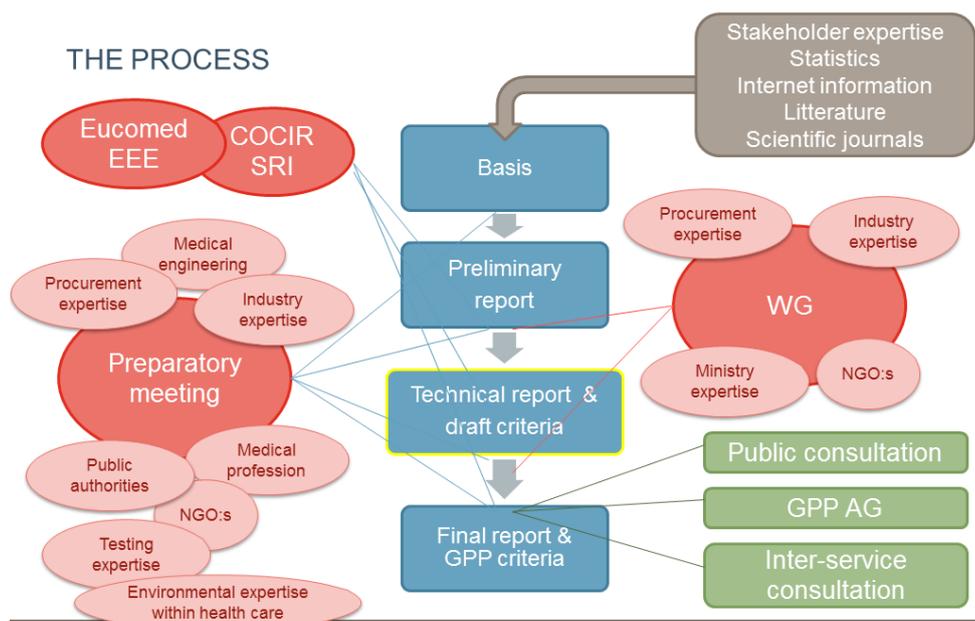


Figure 14. Stakeholder involvement in the criteria development process.

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The stakeholders and expertise have been engaged via 25 meetings in addition to several telephone conferences, e-mails, project room at SEMCo's website and separate telephone calls.

Stakeholders not engaged via meetings have been encouraged to participate in the open consultation.

For more details regarding stakeholder representation, see chapter 4.

## 11.2 FINAL SCOPE

From the initial scope, draft criteria have been developed for the following product groups, thus presenting the final scope:

- Active Respiratory Gas Humidifier
- Autoclaves
- CT (Computed Tomography)
- Dialysis equipment
- Diathermy equipment
- Disinfectant equipment
- ECG equipment
- Endoscopic equipment
- Incubators for babies
- Infusion pumps
- Laser instruments for surgery
- Medical freezers
- Medical lighting (operation lamps)
- Monitoring equipment
- MRI (Magnetic Resonance Imaging)
- Patient warming systems
- Ultrasound
- Ventilators
- X-ray (including mammography)

The product groups present in the original scope and not in this final scope are not included because of insufficient data and lack of time.

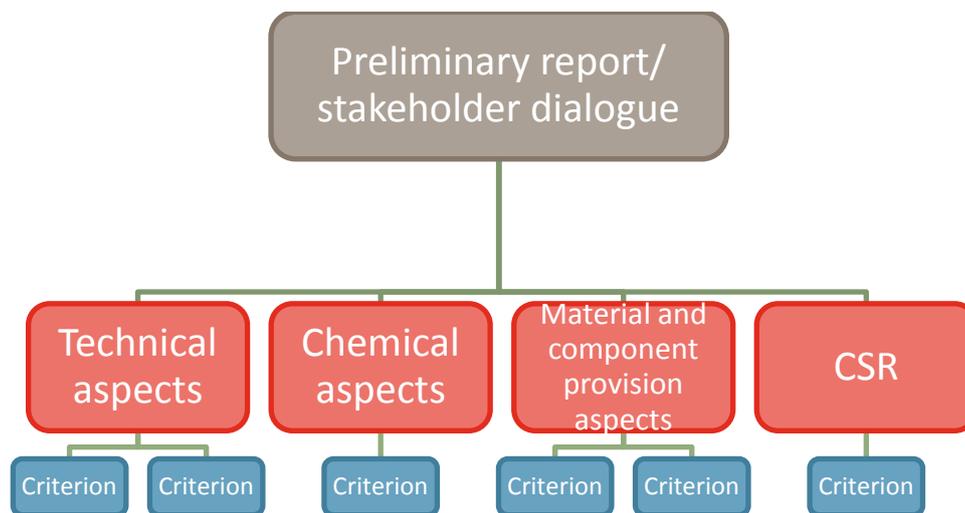
Regarding anaesthesia equipment and intensive care equipment, these were divided into subproduct groups. The most energy using products were prioritised.

## 11.3 CHOICE OF SUSTAINABLE ASPECTS

Four sustainable aspect areas were chosen to elaborate further on the basis of information provided by the preliminary report and the guidance provided by the stakeholder/expert groups. The intention was, with the help of the stakeholder

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expertise, to develop a set of criteria or criterion for each of these sustainable aspect areas. The advantage with sustainable aspect “areas” was that, at times, the expert group was divided into smaller groups representing the specific expertise for each of these aspect areas.



*Figure 15. Illustration of sustainable aspect areas representing four flows of criteria development.*

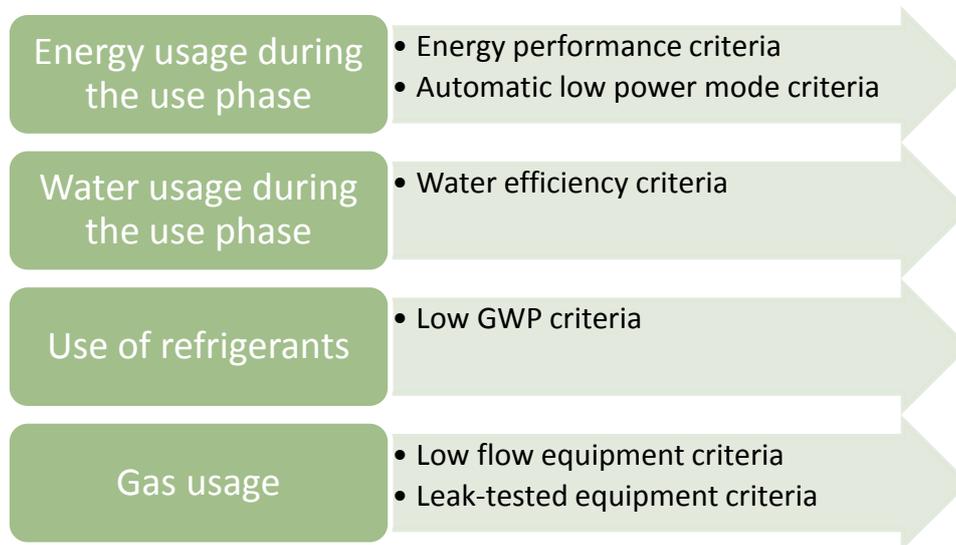
#### 11.4 DEVELOPMENT PROCESS – TECHNICAL ASPECTS

Technical aspects comprise the following environmental aspects identified in the preliminary report:

- Energy usage during the use phase
- Water usage during the use phase in dialysis and disinfectant equipment
- Use of refrigerants with high GWP in medical freezers
- Gas usage in anaesthesia equipment

Discussions and workshops handling these environmental aspects resulted in the proposed criteria illustrated in the Figure below.

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*Figure 16. Illustration of the resulting proposed criteria in expertise discussions and workshops.*

The development of these criteria are described in detail in the following chapters.

#### 11.4.1 ENERGY PERFORMANCE CRITERIA AND AUTOMATIC LOW POWER MODE

Energy performance measuring methods are required in order to set well-formulated energy efficiency criteria. This is important because when the energy performances of the healthcare EEE of the tenderers are measured (in order to establish which equipment is the most energy efficient) it must be accomplished in the same way, so that they are compared on equal terms.

There is a lack of commonly agreed energy performance measuring methods and standards for healthcare EEE in Europe. However, COCIR is in the process of developing energy performance measuring methods for medical imaging equipment. The methods finalised by COCIR were incorporated into the GPP criteria.

Regarding other equipment, dialogues with stakeholders both from industry and hospitals indicated that there are good possibilities to set up energy performance measuring methods in the development of GPP criteria, based on existing standards and modes definitions.

The following need to be well defined in order to set up energy performance measuring methods:

- The different modes and which of the modes are relevant for each equipment
- The use scenario for each equipment
- The power draw of the equipment in each mode

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- The test conditions. These can be conditions such as ambient temperature, how to set up the equipment etc.

The use scenario was discussed if a pre-determined use scenario would be specified by the expert group or left to the individual procurement organisations to determine. It was decided that it would be up to the individual procurement organisations to determine the use scenario as it can vary depending on the hospital.

The power draw of the equipment is to be stated by the tenderer, who needs to register the power draw from the system during each mode, measured according to the specified test conditions.

The energy performance also depends on different types of patient examinations or treatments as well as whether or not equipment is multi-functional. Where this greatly affected the energy performance, this was included in the energy performance measuring method.

Modes were defined and chosen for each equipment as well as test conditions. As far as possible, there was reference to existing standards as quality performance standards or patient safety standards.

The expertise had detailed discussions about test conditions, definitions of different modes and standards for safety performances. One equipment was chosen to work with as pilot equipment in order to come to an agreement on a standardised approach which could be applicable for all equipment.

The conclusion of this work was that the energy performance measuring methods can be developed in accordance with quality/functional or safety performance standards. An example is ISO 15883-1- *Terms, definitions and tests, used for disinfectant equipment* or IEC 62D/80601-2-12- *Particular requirements for basic safety and essential performance of critical care ventilators*.

With the help of SEK (Swedish Elstandard), definitions on different modes were chosen from *COMMISSION REGULATION (EC) No 1275/2008, implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to Eco design requirements for standby and off mode electric power consumption of electrical and electronic household and office equipment*, and these modes were used as applicability check points for every equipment in the criteria development process.

SEK is a non-profit organisation responsible for the Swedish Electro technical Standardisation and coordinating Swedish participation in International and European standardisation as the Swedish National Committee of IEC (International Electro technical Commission) and CENELEC (European Committee for Electro technical Standardisation).

European Standard EN- 50564: 2011, which specifies methods of measurement of electrical power ratings for a range of electrical and electronic household and office equipment, was advised by the expertise to be used for different equipment in the development process. It describes in detail the

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requirements for testing single phase products with a rated input voltage in the range of 100 V a.c. to 250 V a.c, but it may, with some adaptations, also be used with three phase products in support of other, more specific, product standards where it is required to measure power ratings or energy performance. This European Standard was prepared by Technical Committee CENELEC TC 59X, Performance of household and similar electrical appliances.

Sampling methods and test conditions in the standard EN-50564: 2011 have been suggested to be included in a method to measure energy performance for most of the equipment. As far as possible, the procedures in accordance with quality/functional or safety performance standards have also been used. Depending on which safety performance was relevant for the specific equipment in the standard, the expertise chose test conditions and procedures that could be suitable for measuring the energy performance. This means that manufacturers can test the product according to the specific standard and fulfil requirements for safety or quality together with energy performance at the same time during the same test conditions. An example is “typical operating conditions of chronic HD treatments with Haemodialysis” which refers to the standard IEC 60601- 2- 16: 2008 and “stability of incubator temperature” which refers to the standard for infant incubator EN 60601-2-19. Referring to these standards for the power draw measurement was also important concerning the aspect of maintaining a high patient safety standard and the function of the equipment. Minimising energy usage of equipment could otherwise jeopardise this. For example, it is important to measure the energy performance of an infant incubator in active mode while the incubator temperature is the required temperature according to the safety and performance standard of infant incubators.

The following standards that have been discussed and utilised (concerning equipment that was eventually part of the final scope):

- IEC 60601-1:2005 Part 1: General requirements for basic safety and essential performance
- EN 50564, Electrical and electronic household and office equipment – Measurement of low power consumption
- EN 62018, Power consumption of information technology equipment. Measurement methods
- IEC 62D/ 80601- 2- 12 Critical care ventilators, Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- EN- 285: 2006 Sterilisation- steam sterilisers, large sterilisers
- ISO 15883 -4:2008, Washer-disinfectors –Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

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- EN 60601- 2- 2, Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- IEC 62D/60601- 2- 27/Ed.3, Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- EN 60601- 2- 18, Part 2: Particular requirements for the safety of endoscopic equipment
- IEC 60601- 2- 16: 2008 Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment
- EN 60601-2-19, Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators
- EN 60601-2-20, Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators
- EN 60 601-2-22, Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment
- EN 60601- 2- 24, Part 2-24: Particular requirements for the safety of infusion pumps and controllers
- EN 60601- 2- 37, Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- EN 60601- 2- 41, Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis
- IEC 60601-2- 49 Ed.2, Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- EN 60601- 2- 54, Part 2-54: Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy
- EN 61223- 3- 2, Part-3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment
- EN 60601- 2- 44, Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
- EN 80601- 2- 35, Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use
- IEC 61675-1 Ed.1:1998, Part 1- Positron emission tomographs
- IEC 61675-3 Part 3: Gamma camera-based whole body imaging systems

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- ISO- 8185:2007 Active respiratory gas humidifier

Results from the SRI- report, Self-Regulatory Initiative for Medical Imaging Equipment, Eco design target for MRI, by COCIR, have been used for MRI and partly for CT regarding measuring methods for energy performance.

The criteria are expressed as award criteria, since lack of market data made it difficult to set energy performance levels. Now that common energy performance measuring methods are in place, levels can be set when updating the criteria.

Another important energy performance criterion discussed was the requirement of an automatic standby or off function of the equipment. This was carefully discussed considering patient safety aspects. It was suggested that automatic low power mode criteria were relevant for the following equipment: CT, MRI, ECG, disinfectors and ultrasound. These were also expressed as award criteria, since there is uncertainty regarding market data, i.e. fulfilment of the requirement. Stakeholders know that there is equipment complying with the criteria.

Requirements regarding heat dissipation were also meant to be included for MR and CT as draft GPP criteria, but because of lack of time, these criteria were not able to be finalised before the public consultation.

#### 11.4.2 OTHER TECHNICAL ASPECTS

##### 11.4.2.1. Water usage

Stakeholders for relevant equipment were invited to discuss criteria for water usage. The proposal is that the same model as for energy performance regarding test methods can be used. Water usage criteria apply to Washer disinfectant, Flusher disinfectant and Dialysis equipment. A criterion rewarding a low water consumption function was also developed as it enables water saving possibilities in the standby mode. The requirements are suggested as award criteria because of the lack of market data, but there is equipment with low water usage and water saving functions on the market.

##### 11.4.2.2. Gas usage

Gas is used by anaesthesia equipment. Because of environmental, economic, and work situation reasons, it is recommended to keep gas consumption low. And yet it is important not to endanger patient safety and, in minimising gas flow, risk insufficient sedation of the patient. Therefore, suggested GPP criteria regarding gas consumption were carefully selected and resulted in criteria regarding low-flow equipment and leak-tested equipment. They are suggested as award criteria because of the lack of market data, but there is low flow, leak-tested equipment on the market.

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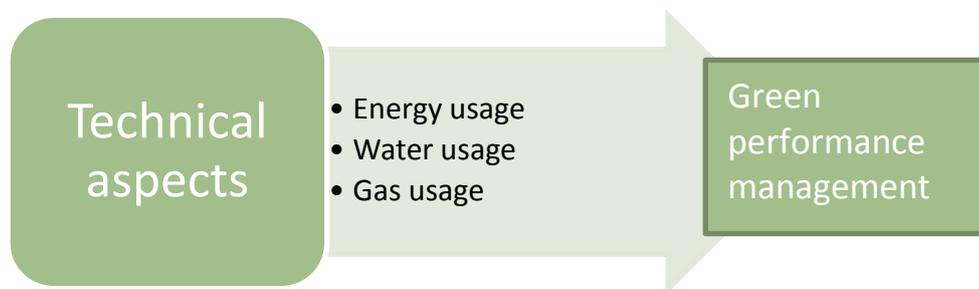
#### 11.4.2.3. Use of refrigerants with high GWP

Medical freezers contain refrigerants that can have high GWP, global warming potential. There are refrigerants with low GWP available. Therefore, a criterion regarding low GWP of refrigerants in medical freezers was suggested. It is suggested as an award criterion because of the lack of market data, but there are low GWP medical freezers on the market.

#### 11.4.2.4. Green performance management of the equipment

Stakeholder discussions led to the usage of the equipment being an important aspect to consider and there is a large potential for environmental improvement. A typical example is to always run dish disinfectors fully loaded. It was discussed how companies and hospitals can work together with, for example, training for the personnel using the equipment. This is already commonplace in a lot of procurement today. Since the standard IEC 60601-1-9 also contains a part regarding equipment documentation to help the user minimise the environmental impact it was decided to develop a criterion based on that. It was also argued that the user must have access to this information from the time of delivery/installation for it to be useful throughout the whole usage phase.

The criterion also affects the environmental aspects of energy, water and gas usage indirectly for the benefit of the environment, see figure below.

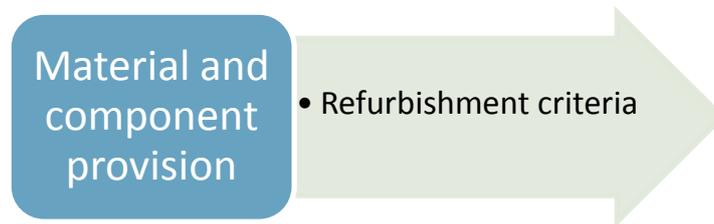


*Figure 17. Illustration of how green performance management is important to lower energy, water and gas usage in healthcare EEE.*

### 11.5 MATERIAL AND COMPONENT PROVISION ASPECTS

Discussions during the criteria development process, handling material and component provision, resulted in the proposed criterion shown in the figure below.

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*Figure 18. Illustration of the resulting proposed criteria in expertise discussions.*

The environmental aspect analysis (see Chapter 6) reveals that material and component provision in the manufacturing phase of the equipment is an important environmental aspect.

The stakeholders and expertise thought it would be very difficult to set criteria regarding composition of materials for all the different equipment. It was therefore suggested to only focus on environmentally conscious design and possibilities for refurbishment.

Since there are standards for healthcare EEE regarding environmentally conscious design (for example IEC 60601-1-9 and IEC 62430), a criterion can be based on these or similar. It was, however, difficult to compare the different tenderers' fulfilment of the criterion, and to know which tenderer would have the product with the best environmental performance.

Regarding component provision, there were discussions on how to form a criterion. It was difficult to find a suitable verification regarding content (for example percentage) of re-used parts in the equipment. However, it was possible to develop a criterion awarding equipment being part of a refurbishment system. The criterion indirectly awards the re-use of parts, components and material. It is suggested as an award criterion because of the lack of market data, but there is equipment that makes up part of refurbishment systems on the market.

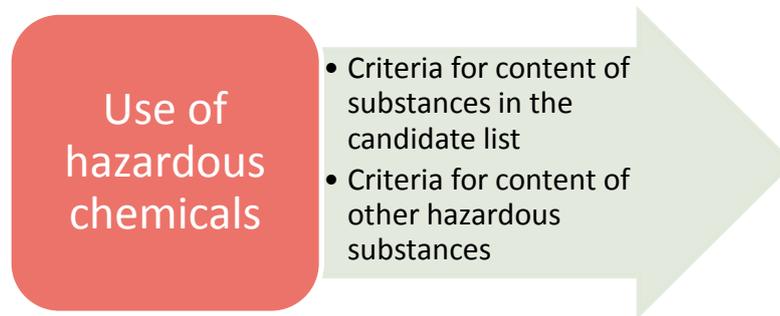
## 11.6 CHEMICAL ASPECTS

Chemical aspects comprise the following environmental aspect identified in the preliminary report:

- Use of hazardous chemicals

Discussions and workshops during the criteria development process, handling this environmental aspect, resulted in the proposed criteria illustrated in the figure below.

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*Figure 19. Illustration of the resulting proposed criteria in expertise discussions and workshops.*

In the environmental aspect analysis (see *Chapter 6*) content of hazardous chemicals is identified as an area to consider when developing GPP criteria for healthcare EEE even though it is not confirmed that chemicals is one of the most important environmental aspects. However, in discussions with the Swedish stakeholder group the importance of developing chemical criteria was emphasised for a number of reasons:

- Hazardous substances are identified as present in medical devices
- Very little is known about the effects on humans and the environment from the chemical cocktail and therefore the precautionary principle should be used as a basis for the work
- The UN chemicals agreement is not on track to meet the goal on sound management of chemicals by 2020
- The Swedish Chemical Agency has recently showed that with current policy instruments the national environmental goal on a Non-Toxic Environment by 2020 will not be attained. Voluntary instruments, such as GPP, are earmarked as one of many ways to move forward
- Most of the Swedish County Councils have ambitious goals on substitution of hazardous chemicals from the articles used in healthcare
- The initial meeting with the stakeholder group on 14 June 2011 showed that some companies are not familiar with their obligations regarding, for example, information about Candidate list substances
- Results from the RFI showed that many companies do not know the chemical content of their equipment

For the above reasons it was decided to develop GPP criteria regarding content of hazardous chemicals. However, it was not obvious in what way chemicals should be tackled. Legislation such as REACH, RoHS (in due course), WEEE and also the MDD, already regulates some important parts but still there is room for improvement. Initially it was suggested that the chemical criteria should cover both the company's ambitions in chemical management and the content of hazardous chemicals in the equipment. The following

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section explains the reasoning and discussion that took place in the stakeholder group and led to the suggested draft GPP criteria for chemicals.

#### 11.6.1 PROCEDURES FOR IDENTIFICATION OF HAZARDOUS CHEMICALS

Based on the knowledge that many companies today do not know what hazardous substances might be in their equipment it was suggested developing a qualification criterion that require companies to have a systematic way of finding this out. It should be mentioned though that some companies (preferably the larger ones) already have systems for this in place but are finding it hard to obtain information from their sub-suppliers regarding substances which are not already covered by legislation—for instance RoHS and Candidate list substances.

The aim of the criterion is for companies to have a systematic way of identifying hazardous chemicals; therefore, it was agreed that the criterion should ask for the companies documented procedures that explains the method for identifying the hazardous chemicals. For instance, how the company acts when contracting new sub-suppliers in order to understand what possible new hazardous chemicals can be found in the new materials, parts, etc. These documented procedures could be part of an environmental or quality management system or be separate documents.

Initially, it was also discussed whether the documented procedures should also contain a method for evaluating possible substitutes to the hazardous chemicals. The stakeholder group reached the conclusion that since there is still lack of data regarding possible substitutes it would be too difficult to demand that this to be part of the procedure.

Obviously, it is necessary to clarify which hazardous chemicals are intended. Since it is already an obligation to be able to give information on Candidate List substances it is presumed that companies already have some kind of procedures regarding identification of these substances. All substances that meet the criterion of being a Substance of Very High Concern according to Article 57 in REACH, are not automatically included in the Candidate list. Therefore, it was suggested that the GPP criteria should be based on the criteria in Article 57 in REACH:

*(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;*

*(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;*

*(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;*

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*(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;*

*(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;*

*(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.*

It has been argued that substances meeting the criteria in Article 57 but not already included in the Candidate List might be subject for inclusion in the immediate future. The Candidate List is updated twice a year, and therefore the suggested GPP criterion is very close to a legislative requirement. Despite this, the stakeholder group found the criterion relevant and suggested it as a core criterion. However, the intention with GPP criteria is to be a driving force which goes beyond legislative requirements. The purchasing authorities shall not be recommended to pursue supervision. Finally, no criterion on chemical management was therefore suggested.

#### 11.6.2 CONTENT OF SUBSTANCES ON THE CANDIDATE LIST

Candidate list substances are substances that have properties that can lead to severe and permanent effects on human health and the environment. There is a wish to minimise the use of these substances within the EU and substances on the Candidate list might be subject for authorisation and in time given a sunset date when the substance can no longer be put on the market or used. As a preventive measure, many organisations and companies already work on substituting Candidate List substances.

It must be borne in mind that although the Candidate list substances are hazardous they most often have a function in the product and it is not always easy to replace. When it comes to Healthcare EEE the patient safety factor is important to consider when working with substitution. The stakeholder group argued that it would not be possible to set a general criterion for all equipment within the scope requesting that no Candidate List substance could be present in the equipment (i.e. criteria in the technical specification). Another way to handle content of Candidate List substances was therefore to award equipment that has no or low content of these substances. In many Swedish County Councils there are political decisions that environmental considerations shall be taken into account when purchasing goods for hospitals, including Healthcare EEE, even if there is a cost increase.

The stakeholder group discussed different award models but came to the conclusion that many organisations and procurers have different ways of awarding contracts and, therefore, no general award scheme is suggested.

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It was also discussed whether the content should be expressed as part of “the homogenous material” in the equipment (according to the definition in RoHS) or “the article” (according to the definition in REACH). Since different member states have different interpretations of the definition of an article it was first suggested to refer to homogenous material, also with regard to the fact that it is EEE, which means there is a strong connection to RoHS. But since the criterion applies for Candidate List substances, which originates from the REACH regulation, it was decided to refer to the definition of an Article in REACH.

How to verify compliance was also discussed within the stakeholder group. A test report or certificate from laboratory analysis of chemical content is of course the most trustworthy proof of compliance but very complicated and expensive. Therefore it was suggested that an assurance from the supplier guaranteeing the chemical content should be sufficient. To make this assurance the supplier must have background documentation from its own sub supplier also guaranteeing the content of substances. This is the way most companies work when securing compliance with RoHS.

### 11.6.3 CONTENT OF OTHER HAZARDOUS SUBSTANCES

Since the Candidate list is general and not specific for Healthcare EEE it was discussed whether it is relevant to refer to the whole candidate list or whether it would be possible to single out substances surely relevant for Healthcare EEE. Since the RFI gave no new information on what substances are present in Healthcare EEE it was decided to emanate from the list of substances generally present in Healthcare EEE, see Table 4 in this report. This list is not specific for Healthcare EEE either but it reflects substances commonly found in EEE. Since production of electro-technology is mostly executed in the same factories and countries, the stakeholder group agreed that it could be a relevant list from which to start.

It was discussed whether it is possible to refer to this full list of substances in Table 4 but the stakeholders argued that it would be better to make a selection of substances based on some defined criteria. The criteria were finally decided to be the following:

1. The substance is meeting the criterion for classification in Category 1 in Article 57 (a-f) in REACH Regulation 1907/2006/EG i.e. a substance classified in the hazard class carcinogenicity category 1A or 1B (in accordance with section 3.6 of Annex I to Regulation [EC] No 1272/2008) will be selected while a substance classified in the hazard class carcinogenicity Category 2 will not be selected.
2. The substance must not already be regulated in legislation such as RoHS, REACH etc. i.e. Candidate List substances and RoHS substances will not be selected.
3. The substance must have a function (i.e. flame retardant, softener, etc.) in the equipment and not be an impurity.

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4. The substance must not already have an exemption/permission to be used in a specific application (Comparably mercury in low-energy bulbs).

The above criteria were then used to single out the substances relevant for a comprehensive criterion on hazardous substances. The selected substances were:

- Beryllium, CAS 7440-41-7
- Beryllium oxide, CAS 1304-56-9
- Dinickel trioxide, CAS 1314-06-3

Some concerns were raised that the original list of substances (Table 4) is based on a report only available in Swedish and that the references are not properly balanced. It was also argued that the environmental benefit of suggesting a criterion like this for all equipment within the scope is very small. It is rather an administrative burden for both procurers and tenderers. Finally, it was therefore decided to only suggest a criterion regarding beryllium known to be present in X-ray and CT equipment.

The same discussions regarding article or homogenous material, proposal for verification and award scheme as described above also applies for this criterion.

## 11.7 SOCIAL ASPECTS

There has been an ongoing discussion within the Commission on expanding the scope of GPP-criteria to SPP-criteria; therefore, social aspects has been a part of the scope for this project. Recently, DG Environment decided not to include the social aspects within the current GPP tool. As explained in the mission of the project, the upcoming EU GPP criteria for medical devices will also be adopted in Sweden nationally. Since social criteria nowadays are commonly used on a Swedish level, a social criterion for healthcare EEE will be suggested to be included in the Swedish GPP criteria set.

The following sections explain the reasoning behind the suggested draft criterion.

### 11.7.1 CONTRACT PERFORMANCE CLAUSE

A contract performance clause sets out how a contract should be performed. Social considerations may be included in the contract performance clauses, if they are linked to performance of the contract, if they are published in the contract notice and if they comply with EU law. Contract performance clauses are obligations which must be accepted by the successful tenderer and which relate to the performance of the contract. Tenderers must therefore meet such conditions if the contract is awarded to them ("Buying social", p.43).

According to the European Commission, contract performance clauses are the most appropriate stage of the procedure to include social considerations

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relating to the working conditions of those involved in performance of the contract. Contracting authorities may in the contract performance clauses include social considerations regarding working conditions, such as prohibition of child and forced labour, health and safety requirements, minimum wage obligations and decent work standards. This has particular implications for dealings in and with countries outside the EU. When such requirements are also imposed on subcontractors, contracting authorities should ask the main contractor to provide proof of compliance, either by reference to specific certification schemes (where such schemes exist) or by any other reliable means.

#### 11.7.2 ONE TIME DELIVERIES AND ALREADY PRODUCED GOODS?

Contract performance clauses are appropriate to use for a framework agreement or procurement with a contract period. In situations where the procurement is only a one time delivery or goods which have already been produced, it is not appropriate to use contract performance clauses.

If the procurement, however, is a framework agreement or goods which in fact are being produced after the order of the contracting authority, social criteria as contract performance clauses can be used.

#### 11.7.3 THE CRITERION SUGGESTION

Medical equipment EEE is high-tech products. The lack of respect for fundamental working conditions has mainly been shown in the production of low-tech products, such as surgical instruments, gloves and needles. Although high-tech products are generally being manufactured in the United States and Europe, components for these products are being manufactured all over the world, including in so-called low cost countries. It is therefore important to consider the whole supply chain in the procurement of medical equipment EEE.

The criterion suggestion refers to basic standards on working conditions; the ILO core conventions and the UN convention on the rights of the child, article 32. The supplier should also respect national legislation concerning safety and health and employment legislation in the country of manufacture.

Suppliers will have procedures to manufacture products produced under conditions compliant with fundamental working conditions in the supply chain. This means that the supplier must have a person who is responsible for social requirements, the company must have knowledge about where the products are being supplied are manufactured, the supplier should have made a risk analysis for the supply chain etc. (compare the [questionnaire](#)). A company with production in low cost countries can seldom guarantee they do not violate fundamental working conditions in any part of the supply chain. The suppliers will therefore show that they work actively to minimise these risks.

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While setting social criteria in procurement, it is necessary to follow it up to verify that the supplier respects its obligations. Contracting authorities should have a follow-up process to make sure it is being fulfilled.

#### 11.7.4 HOW FAR DOWN THE SUPPLY CHAIN DOES THE CRITERION APPLY?

The goal is that the social criteria apply to whole supply chain. Contracting authorities must focus follow-up on the contracting partner. Procurement directives do not enable contracting authorities to set criteria on sub suppliers; however, they can ask their supplier to set social criteria on their suppliers and sub suppliers. Contracting authorities should therefore focus on suppliers routines to deal with these issues in their supplier contacts.

It is important for the supplier to communicate the social criteria in the supply chain. The greater knowledge and undertaking the supplier has in the work to improve working conditions, the more likely that the supplier also continues to work with these issues after the contract has expired. Social criteria also increase the possibility for the supplier to strengthen the suppliers' competition possibilities in future procurement.

#### 11.7.5 FOLLOW-UP PROCESS

Contracting authorities who set social criteria must make sure the criteria are being met by the supplier. The follow-up can be seen as a step by step process. If certificates who confirm that the supplier. Contracting authorities should therefore use a process to fulfil the follow-up.

The follow-up of social criteria is important in many ways. The follow-up makes sure that the contracting authority is serious with the social criteria. It is also important to make sure that the principle of equality is respected and to make sure that only a serious company tenders a public contract.

#### 11.7.6 FOLLOW-UP TEMPLATES

Templates can be used to simplify the follow-up, both for contracting authorities and suppliers. By using the templates, it is clear to the supplier what is being expected of them, how the follow-up is going to be fulfilled and which routines the supplier must have in their business to make sure that they do not violate basic human rights in their supply chain.

The recommended templates consist of the following:

- Questionnaire (self-declaration for the supplier)
- Text explaining the questionnaire (for the supplier)
- Assessment template (for the contracting authority)

The follow-up process can be described in the following steps:

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1. The contracting authority can ask the supplier to answer the questions in the questionnaire (recommended six months after the contract enters into force). To help the supplier do this, a template explaining the questionnaire contains information on how to fill in the questionnaire.
2. After receiving the questionnaire from the suppliers, the contracting authority can use the assessment template to evaluate the answers. If the answers are not satisfactory, the contracting authority should ask the supplier to complete the questionnaire with correct information. The contracting authority must also consider how to deal with the situation if the supplier does not meet the criteria that have been set in the contract clauses.
3. Contracting authorities should have the possibility to follow through a monitoring inspection on the production site. This should be managed by an auditor with experience in this field.

#### 11.7.7 OTHER POSSIBILITIES TO SET SOCIAL CRITERIA IN THE PROCUREMENT PROCESS

##### Selection criteria: technical capacity

During the selection process, contracting authorities have the possibility to assess candidates' ability to deliver the requirements specified in the contract. The Procurement Directives contain an exhaustive list of technical capacity selection criteria, which can be applied to justify the choice of candidates. It is therefore not compliant with the directives to set out different selection criteria from those in the Procurement Directives.

Social considerations may be included in the technical selection criteria only if the achievement of the contract requires specific "know-how" in the social field. Such "know-how" can include access to personnel with knowledge to deal with social issues, technical equipment for social protection or technical facilities available to cover social aspects. Evidence of the economic operators' technical abilities may be provided by one or more of the exhaustive means specified in the Directives (65), such as evidence of previous contracts completed, a description of the technical facilities used, the educational and professional qualifications of the contractor's personnel, details of the manpower of the service-provider and numbers of managerial staff and details of the proportion of the contract that may be subcontracted.

However, criteria concerning the working conditions of those involved in performance of the contract are not selection criteria within the scope of the meaning of the Procurement Directives ("Buying social", p. 44, footnote 84). It is therefore not suggested to set out social criteria for medical equipment EEE in the selection criteria.

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### Technical specifications

Technical specifications must be linked to the subject matter of the contract. It is possible to include social aspects in the technical specifications if they can be connected to the subject matter of the contract, such as technical requirements aiming to avoid accidents on the construction site. Requirements not connected to the product or the service itself, such as a requirement relating to the way in which an undertaking is managed, are not technical specifications within the scope of the meaning of the Procurement Directives (“Buying social”, s. 29).

Requirements relating to the working conditions of those involved in the production process of the supplies to be procured cannot be taken into account in the technical specifications, as they are not technical specifications within the scope of the meaning of the Procurement Directives. It is therefore not appropriate to set social criteria in medical equipment EEE as technical specification.

### Awarding the contract

During the evaluation of quality of tenders, contracting authorities can use award criteria to decide which tender is the best. When the contracting authority chooses to award the contract to the most economically advantageous tender, other criteria can be taken into account in addition to the price.

These criteria can include e.g. quality, price, technical merit, aesthetic and functional characteristics, cost-effectiveness and social characteristics. The Procurement Directives explicitly allow social considerations to be included in award criteria.

Award criteria must be linked to the subject matter of the contract and be specific and objectively quantifiable, previously published and must comply with EU law. Other additional criteria, not linked to the subject matter of the contract, can be taken into account only if this concerns two or more equivalent tenders.

Social considerations concerning working conditions are difficult to link to the subject matter of the contract. It would generally not be possible to include them in the award criteria for the contract, except as an “additional criterion” to make the difference between two equal tenders.<sup>6</sup> Social criteria concerning labour conditions in the production of medical equipment EEE may be taken into account in the awarding of the contract, but only if the contracting authority has to deal with two (or more) equivalent tenders. The suggestion is therefore to include these criteria in the contract performance clauses.

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<sup>6</sup> As accepted by the CJEU in case C-225/98 (49-51).

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## 12 PROPOSAL FOR CORE AND COMPREHENSIVE CRITERIA

The proposed draft GPP criteria for healthcare EEE are presented in this section.

It is proposed to set core and comprehensive criteria for healthcare EEE. The proposed GPP criteria are designed to reflect the key types of environmental impact. This approach is summarised as follows:

KEY ENVIRONMENTAL IMPACTS	GPP APPROACH
<ul style="list-style-type: none"> <li>Energy usage in the use phase (e.g. emission of GHG emissions and air pollution in energy production)</li> <li>Water consumption in the use phase, dialysis, disinfectors (Water scarcity)</li> <li>Gas consumption in the use phase, anaesthesia equipment (e.g. emission of greenhouse gases)</li> <li>GWP of refrigerants in medical freezers (Global warming, ozone depletion)</li> <li>Use of materials (Scarcity of resources)</li> <li>Content of hazardous chemicals (e.g. Carcinogenic properties)</li> </ul>	<ul style="list-style-type: none"> <li>Purchase energy efficient equipment</li> <li>Purchase equipment with automatic low power mode</li> <li>Purchase equipment supplied with green performance management instructions</li> <li>Purchase water efficient dialysis and disinfectant equipment</li> <li>Purchase low-flow, leak-tested anaesthesia equipment</li> <li>Purchase medical freezers containing refrigerants with low GWP</li> <li>Purchase equipment that is part of a refurbishment system</li> <li>Purchase equipment with low levels of hazardous substances</li> <li>Purchase equipment that in the production phase fulfils social requirements regarding working conditions, health and safety and decent work standards<sup>7</sup></li> </ul>

<sup>7</sup> Social and ethical impact will only be part of Swedish criteria, not EU criteria, since they are limited to green procurement. Social considerations can be included according to the "Buying Social Guide"

<http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=978&furtherNews=yes>

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- Social and ethical impact such as workers' conditions etc.

The order of the type of impact does not necessarily reflect their importance.

There are two different levels of criteria in EU GPP criteria:

- The core criteria are those suitable for use by any contracting authority across EU Member States and address the key type of environmental impact. The criteria are designed to be used with minimum additional verification effort or cost increases.
- The comprehensive criteria are for those who wish to purchase the best products available on the market. These may require additional verification or a slight increase in cost compared to other products with the same functionality.

## 12.1 PROPOSAL OF DRAFT CRITERIA

The proposed draft EU GPP criteria can be reviewed in the **draft criteria document** on the SEMCo webpage, see [www.msr.se/criteria-work/medtech](http://www.msr.se/criteria-work/medtech).

## 12.2 VERIFICATION ISSUES

For healthcare EEE, there are no eco-labels available yet, where a set of criteria has to be fulfilled according to the label and the check of compliance with these criteria involves submitting documents in the form of declarations of compliance by the producer or by the supplier, technical and/or product safety sheets; laboratory tests results, etc.

Appropriate verifications have been discussed and proposed in the draft GPP criteria by the expertise and stakeholders involved in the criteria development process. Examples are: written statements from the manufacturers and/or supplier, technical documentation including test report and copy of instruction manual. Verification procedures are indicated in the verification section of the criteria document for a given product for each criterion separately.

Certain criteria have been proposed by expertise to be verified with a third party verification, because of the nature of the criteria, i.e. the degree of high technical complexity implies very accurate and correct(for example) energy performance measurements.

## 12.3 ENVIRONMENTAL PERFORMANCE – MOTIVES FOR THE DRAFT CRITERIA

The criteria motives provide environmental arguments for each criterion provided in the criteria document.

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### 12.3.1 QUANTIFIED ENVIRONMENTAL PERFORMANCE OF THE CRITERIA

Quantified environmental performance of the criteria can be found in Table 6 in Chapter 13.

### 12.3.2 MOTIVE OF THE TECHNICAL SPECIFICATION

#### User instructions for green performance management

The purpose is to give the users of the equipment access to information on how the equipment shall be used to minimise the environmental impact as much as possible. It is important that users have access to this information from the time of delivery/installation of the equipment so that correct usage is possible throughout the whole usage phase.

### 12.3.3 MOTIVES OF THE AWARD CRITERIA

#### Content of substances on the candidate list

Candidate List substances are substances that have serious properties for both humans and the environment. They meet the criteria of being carcinogenic, mutagenic or toxic to reproductive health (CMR-substances) or persistent, bio accumulative or toxic (PBT) or very persistent and very bio accumulative (vPvB) or have other serious properties such as endocrine disrupting properties. The risks resulting from their use must be properly controlled and the substances gradually replaced when possible. The purpose of this criterion is to give an incentive to replace these unwanted substances and award equipment that is free from them.

#### Content of other hazardous substances

Beryllium and beryllium oxide are substances that meet the criteria for Substances of Very High Concern, but these substances are neither included in the Candidate list nor regulated in any other legislation. The substances are known to be present in electrical and electronic components. The purpose of this criterion is to give an incentive to replace these unwanted substances and award equipment that is free of them.

#### Energy performance and automatic low power mode

The purpose of these criteria is to award equipment with lower energy consumption and equipped with a low power mode in order to minimise the environmental impact as much as possible.

Available life-cycle analyses (LCA) indicate that for healthcare EEE, energy consumption in the use phase is significant and results in various environmental aspects. In COCIR's SRI study on ultrasound products, LCA data show that on average, energy consumption during the use phase



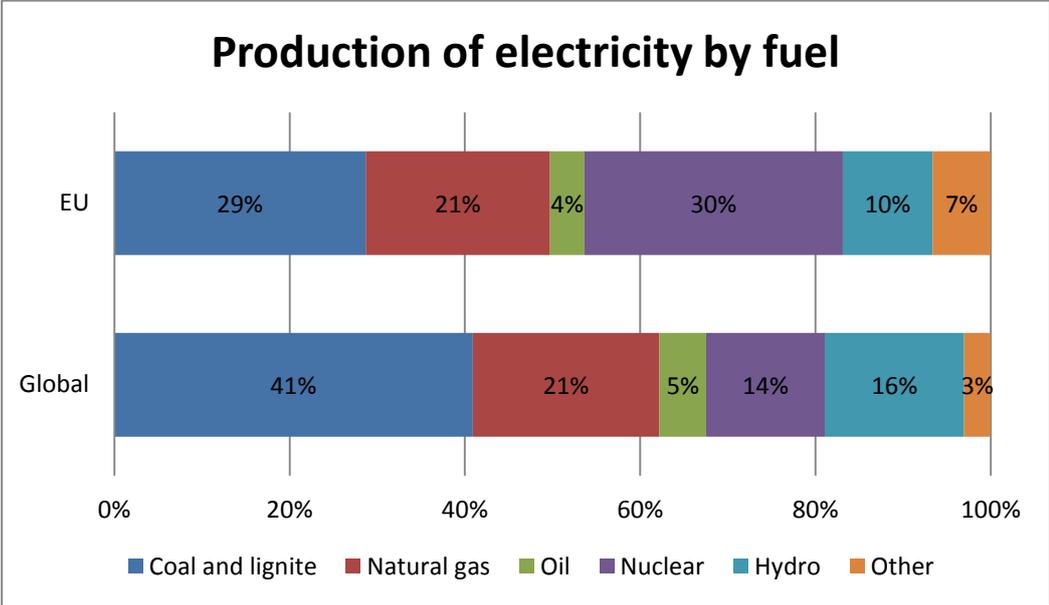
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accounts for approximately 83% of the total life-cycle environmental impact of ultrasound products. Studies performed by manufacturers come to the same conclusion for other product categories of healthcare EEE.

In a study on MRI systems by a manufacturer, a significant reduction of energy could be attained by using efficient gradient and electronics design as well as innovative water-cooling technology. The system used 41% less energy than previous generation systems.

Therefore, energy consumption during the use phase for all selected healthcare EEE is identified as an important environmental aspect, and therefore has high potential for improvement.

Extraction, conversion and use of energy result in different environmental aspects. The most significant environmental aspects are related to emissions from combustion of fuels. Use of fossil fuels lead to an increase in greenhouse gas in the atmosphere, emissions of acidifying substances and exhaust fumes hazardous to both health and the environment. Globally, 67% of the electricity production is based on fossil fuels. The corresponding value in the EU is 54%<sup>8</sup>. Use of renewable energy sources can result in other environmental problems, such as a conflict of interests between cultivation of biofuels or food or restricted access for fish in rivers regulated for hydropower.



The most direct way to reduce the environmental impact and whole-life energy costs is to reduce energy consumption itself – this can be done through energy efficiency improvements in the procurement of energy efficient products. Products offered on the market differ quite significantly in their energy consumption in the different modes (on, sleep, off etc.) and the introduction of energy efficient procurement criteria can make a major difference.

<sup>8</sup> Swedish Energy Agency and Eurostat.

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### Water consumption

The purpose of these criteria is to award equipment with the lowest water consumption in order to minimise the environmental impact as much as possible. Only 0.5% of the world's water resources are available to provide for the freshwater needs of our planet's ecosystem and population<sup>9</sup>.

### Refurbishment

The purpose of this criterion is to award refurbishment of the equipment, in order to minimise the need for new materials, components and parts in the manufacturing phase. Compared to new equipment, refurbishing medical equipment results in a much lower ecological footprint:

- Components and materials are recycled
- Valuable resources are saved
- Emissions of CO<sub>2</sub> are reduced
- Chemical substances are reduced
- Fewer raw materials are consumed
- Less energy is used (Philips, 2012)

### Refrigerant with low GWP in medical freezers

Refrigerants can be very potent global warming substances, and can have a GWP as high as 3300. This criterion will award low GWP refrigerants according to the substitution principle, in order to reduce the handling of high GWP substances and the risk of them leaking into the environment (GWP is the global warming potential of a substance, and indicates the equivalent number of kilos of CO<sub>2</sub> of 1 kg of the substance concerned).

### Gas consumption in anaesthesia equipment

Reduced gas consumption will reduce the use of potent global warming gasses: laughing gas N<sub>2</sub>O (with a GWP<sub>100</sub> of 298) and other anaesthesia gasses: isoflurane (with a GWP<sub>100</sub> of 350), sevoflurane (with a GWP<sub>100</sub> of 575), and desflurane (with a GWP<sub>100</sub> of 1526). The reduction of gases also benefits the working environment for hospital employees.

## 12.3.4 MOTIVE FOR THE CONTRACT PERFORMANCE CLAUSES

### Socially responsible production

The purpose of this contract performance clause is to contribute to better working conditions for the people working in the electronics industry. Today, most components for healthcare EEE are produced in low cost countries.

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<sup>9</sup> <http://waterforworld.net>

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Investments from companies are often very coveted and competition is fierce, which contributes to forcing prices down and requires high production. Different ethical problems are present at all levels of the supply chain, for instance use of harmful chemicals, forced labour, low salaries and other problems in the working environment. The position of workers is often vulnerable with unsecure employment, and violation of employee rights also occurs. It can also be difficult to form a trade union and sometimes this can also lead to dismissals.

### 13 ENVIRONMENTAL, ECONOMIC AND SOCIAL IMPACT OF THE CRITERIA

#### 13.1 CONNECTING ENVIRONMENTAL IMPACT AND HEALTH- SOCIAL IMPACT

The most important task of healthcare facilities is to promote health. Climate change is having an impact on human health. It would therefore be a natural consequence for healthcare facilities to decrease its' global warming impact as this is leading to increased poor health across the world.

The World Health Organization (WHO) has reported that climate change:

- Increases air pollutants such as sulphur dioxide, nitrogen oxide, carbon dioxide and mercury
  - These lead to an increased disease burden in the general public, including conditions such as cardiovascular diseases, asthma and other respiratory illness
- Decreases agricultural production in some of the least developed countries
  - This increases famine
- Encourages the spread of infectious diseases and increases transmission of diseases through unclean water and through contaminated food
  - These include cholera, diarrhoeal diseases, malaria and dengue

In sum, climate change threatens to slow, halt or reverse the progress that the global public health community is now making against many of these diseases.

As an example, in the Midwest of the United States a 200-bed hospital using 7 million kWh/year incurs over US\$ 1 million a year in public health costs and US\$ 107 000 a year in direct health costs, according to estimates by Practice Greenhealth.

The promotion of climate-friendly healthcare can also provide the co-benefit of increased access to primary care in developing countries around the world. (HCHW, 2012) According to stakeholders, resource-efficient equipment can

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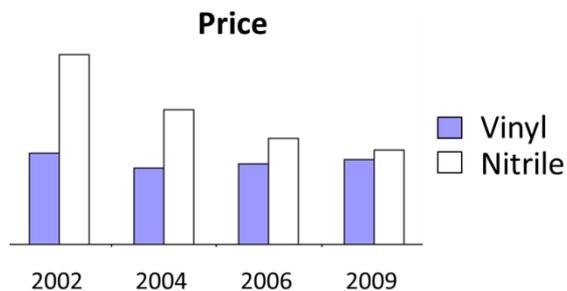
enable countries with poor resources to increase their use of equipment and thus improve their health services.

### 13.2 ECONOMIC IMPACT

GPP criteria might increase costs, but some cost-saving examples are illustrated in Table 6 below. LCC:s (Life-cycle Costing Tools) are sometimes used in procurement of healthcare EEE. Energy efficient products can often prove to be cost-saving when including the cost of operation.

This is important for those regions and county councils with political climate goals such as decreasing electricity usage by half in all hospitals by the year 2030. These hospitals are looking at ways to cut the electricity usage of healthcare EEE.

There is also potential for lowering the costs of products with higher environmental performance as sales volumes increase. This is illustrated by the example of gloves procurement in Stockholm County Council between 2002-2009. At first, the glove with higher environmental performance was twice as expensive, but as sales volumes increased, the price difference in 2009 was only 10%. This has also been shown regarding infusion units.

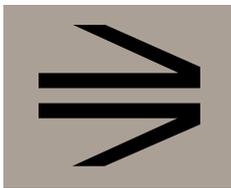


*Figure 21: Illustration of price progress of products with higher environmental performance.*

Companies investing in products with high environmental performance can also benefit economically. Examples show increases of “green” product sales to 12% to 20% of total sales in the recent year, representing an important part of the revenue stream.

### 13.3 EXAMPLES OF ENVIRONMENTAL, ECONOMIC AND SOCIAL (PATIENT) BENEFITS PER EQUIPMENT

An attempt is made below to summarise examples of the benefits of equipment with high environmental performance. The same equipment can also prove to be beneficial to the patient and to save costs. These are examples to illustrate an overview of possible benefits (i.e. that benefits are possible at all) rather than detailed descriptions which consider exactly which examination or operating mode is performed, which comparison is made or which exact model is described.



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Benefits are in comparison with either a predecessor, a standard or similar models on the market. Sources of information are product declarations collected from supplier websites and questionnaire results from the RFI in the market analysis. If a benefit or equipment is not present in the table below, the reason is lack of information.

Example of healthcare EEE	Environmental benefit	Economic benefit	Social benefit – patient benefit
Anaesthesia	<ul style="list-style-type: none"> <li>~22 kg CO<sub>2</sub>/per anaesthetic procedure (~200 million anaesthetics worldwide) global emissions of inhalation anaesthetics have a climate impact comparable to that from the CO<sub>2</sub> emissions from one coal-fired power plant or 1 million passenger cars (4.4 million tonnes of CO<sub>2</sub>) (AAGBI, 2011)</li> </ul>	<ul style="list-style-type: none"> <li>Reduction of costs with low-flow</li> </ul>	<ul style="list-style-type: none"> <li>Less anaesthetics</li> </ul>
Autoclave	<ul style="list-style-type: none"> <li>20% more energy efficient</li> </ul>		
CT	<ul style="list-style-type: none"> <li>3% to 64% more energy efficient</li> <li>6% weight reduction</li> <li>98% recyclable materials</li> <li>45% energy savings during thorax examinations<sup>1</sup></li> <li>85% energy savings during cardiac examinations<sup>1</sup></li> <li>All substances</li> </ul>	<ul style="list-style-type: none"> <li>Annual savings of over \$3300 per CT system</li> <li>Reduction of on-going costs from electricity and air-conditioning</li> </ul>	<ul style="list-style-type: none"> <li>Dose reduction of 15% to 68%</li> <li>Fast</li> <li>Can distinguish between different tissue types in a single scan</li> <li>Sharp and</li> </ul>



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	<p>contained in the product and its packaging are documented</p> <ul style="list-style-type: none"> <li>• Complete systems and their components are taken back and refurbished</li> <li>• 33,000 kWh per machine annually, 20 metric tons of CO<sub>2</sub> emissions, equivalent to the annual CO<sub>2</sub> emissions of four cars</li> </ul>		<p>detailed images</p> <ul style="list-style-type: none"> <li>• Dose reduction to less than one millisievert for cardiac examinations</li> </ul>
Dialysis	<ul style="list-style-type: none"> <li>• 35% to 50% less energy usage</li> <li>• 28% water reduction</li> </ul>	<ul style="list-style-type: none"> <li>• 50% less operating costs</li> </ul>	
ECG	<ul style="list-style-type: none"> <li>• Reduced weight by 5%,</li> <li>• 50% reduction of lead in electronic components</li> <li>• 12% less energy usage</li> </ul>		
Mammography	<ul style="list-style-type: none"> <li>• 46% reduction in energy use</li> <li>• 13% reduction in product weight</li> </ul>		<ul style="list-style-type: none"> <li>• 20% radiation dose reduction</li> </ul>
Medical lighting – surgical lamp	<ul style="list-style-type: none"> <li>• 49% (from LED to halogen) (U.S. 0.06 TWh annually) (Tuenge, 2012)</li> </ul>	<ul style="list-style-type: none"> <li>• Savings of 0.03 TWh annually in the US (Tuenge, 2012)</li> </ul>	
Monitoring	<ul style="list-style-type: none"> <li>• 8% to 52% less energy usage</li> </ul>		



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equipment			
MRI	<ul style="list-style-type: none"> <li>• 14% to 50% less energy usage (business as usual: operating an MR can produce about 90 tons of CO<sub>2</sub> annually)</li> <li>• Reduction of product mass up to 20% to 36%</li> <li>• No helium consumption during normal usage</li> <li>• 95% recyclable materials</li> <li>• Reduces annual electricity usage by approximately 60,000 kWh, equivalent to the annual electricity consumption of five households, 35 metric tons of CO<sub>2</sub>, equivalent to the annual emissions of seven cars</li> </ul>	<ul style="list-style-type: none"> <li>• \$5800 per year</li> <li>• Saves site, electricity and construction costs</li> <li>• Low installation costs</li> <li>• Low connection values for energy and cooling</li> <li>• Lower operating costs</li> </ul>	<ul style="list-style-type: none"> <li>• Increased patient comfort through 70 cm Open Bore Design</li> <li>• Enhanced image quality by optimising the homogeneity</li> <li>• Patient comfort increased considerably by means of reduction in acoustic noise</li> <li>• Improved diagnosis</li> </ul>
SPECT/C T	<ul style="list-style-type: none"> <li>• 64% reduction in energy use</li> <li>• 59% reduction in product weight</li> </ul>		
US	<ul style="list-style-type: none"> <li>• Energy savings of 18% to 87%</li> <li>• 99% recyclable materials</li> <li>• 40% less mass</li> <li>• No mercury in flat panel display or in keypad backlighting battery-saving</li> </ul>	<ul style="list-style-type: none"> <li>• 1300 kWh less electricity per year</li> </ul>	<ul style="list-style-type: none"> <li>• Decreased scan time 12% to 25%</li> <li>• 2-5 additional patients per 10-hour day of</li> </ul>



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	display		<ul style="list-style-type: none"> <li>operation</li> <li>Enhanced image acquisition and quality</li> <li>Instant power up</li> <li>Improved diagnosis</li> </ul>
X-ray	<ul style="list-style-type: none"> <li>15% to 78% more energy efficient</li> <li>6% to 24% weight reduction</li> <li>96% recyclable materials</li> <li>All substances contained in the product and its packaging are documented</li> <li>Complete systems and their components are taken back and refurbished</li> <li>Up to 40% of a X-ray tube consists of reused parts</li> <li>Stand-by mode saves energy by up to 80%</li> </ul>		<ul style="list-style-type: none"> <li>Dose reduction of 12% to 66%</li> <li>Faster and more efficient examinations, higher patient throughput</li> <li>High image quality</li> </ul>
Refurbishment	<ul style="list-style-type: none"> <li>A reduction of 20,000 tons of CO<sub>2</sub> per year. Studies recently showed that this resembles the electric power consumption of approximately 5700 households or the CO<sub>2</sub> storage of around 32 hectares of tropical rain forest</li> </ul>	<ul style="list-style-type: none"> <li>quality comparable to a new system at up to 30% lower purchase cost</li> </ul>	<ul style="list-style-type: none"> <li>refurbished systems with latest technology</li> </ul>



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*Table 6: Summary of environmental, economic and social benefits of some examples of healthcare EEE.*

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## APPENDIX I: ABBREVIATIONS

BBP: Butyl benzyl phthalate

CED: Cumulative Energy Demand

COCIR: The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

CRT: Cathode Ray Tube

CT: Computed Tomography

DBP: Dibutyl phthalate

DEHP: Diethylhexyl phthalate

DIBP: Diisobutyl phthalate

DIDP: Diisodecyl phthalate

DINP: Diisononyl phthalate

DNOP: Di-n-octyl phthalate

ECG: Electrocardiography

EEE: Electrical and Electronic Equipment

ELCD: European Reference Life-cycle Data Systems

EPD: Environmental Product Declaration

GDP: Gross Domestic Product

GER: Gross Energy Requirement

GPP: Green Public Procurement

GWP: Global Warming Potential

HBCDD: Hexabromocyclododecane

IPP: Integrated Product Policy

LCA: Life-cycle assessment/analysis

LCD: Liquid Cristal Display

LCI: Life-cycle inventory

MCCP: Medium Chain Chlorinated Paraffins

MEEuP: Methodology for the Ecodesign of Energy-using Products

MI: Molecular Imaging

MRI: Magnetic Resonance Imaging

NGO: Non-governmental Organisation

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ODP: Ozone Depletion Potential

PEP: Product Environmental Profile

PET: Positron Emission Tomography

REACH: Regulation (EC) No [1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

RFI: Request For Information

RoHS: Directive [2002/95/EC](#) of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

SCCP: Short Chain Chlorinated Paraffins

SPP: Sustainable Public Procurement

WEEE: Directive [2002/96/EC](#) of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment

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## APPENDIX II: LIST OF STAKEHOLDERS

Abbott Scandinavia  
 AD Medical AB  
 Adolesco AB  
 AGA

Agence française de sécurité sanitaire des produits de santé (Afssaps)

Agencia Española de Medicamentos y Productos Sanitarios  
 Agfa Healthcare Sweden AB  
 AIOLOS Medical AB  
 Airsonett AB  
 AISE  
 Albemarle  
 Ambu A/S  
 Andalucía Health Care  
 ANEC  
 Anmedic  
 Arector  
 Aspira Medical  
 B.Braun Medical AB  
 Bard  
 BASF  
 Baxter Medical AB  
 BAYER  
 BBS medical  
 BEUC  
 BK Medical  
 BMA  
 BUSINESSEUROPE  
 C2DS, French National Committee of Sustainable Development in Healthcare  
 CareFusion AB/ Cardinal health alaris f d jakamed  
 Carl Zeiss AB  
 CEA-PME  
 Cefic

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CEI-Bois, the European Confederation of woodworking industries  
 Central Project Management Agency, Lithuania  
 CEPI  
 Climate and Health Council  
 COCIR  
 CompuGroup Medical  
 CONSIP S.p.A.  
 Covidien  
 DEFRA UK  
 DG Market  
 DG Enterprise and Industry  
 DG Sanco  
 Diacor  
 Diaspec AB  
 Distributed Medical Sverige AB  
 Dornier  
 Dräger  
 Dräger Medical  
 ECHA  
 EEB  
 Elekta AB  
 EPAGMA  
 EPEE  
 EPF  
 EU eco-label coordinator EEB and BEUC  
 Eucomed  
 EUEB - Competent Bodies  
 Eurocommerce  
 EUROFER  
 European Professionals on Health and Environment (ephe)  
 European Public Health Alliance  
 European Society for Research and Prevention on Environment and Health  
 (European SREH)  
 Fair Med Care  
 Federal Agency for Medicines and Health Products  
 FEICA, the Association of European Adhesive and Sealant Industry  
 Fresenius  
 Fuji Film  
 Gambro AB  
 Gammadata Instrument AB  
 GE Healthcare IT AB

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GE Medical systems Sverige AB  
 Getinge AB  
 German Federal Ministry of Health  
 GPP Advisory Group  
 HCWH  
 Health and Environment Alliance  
 Hermes Medical Solutions  
 Hewlett Packard  
 HOPE  
 IBM Sverige AB  
 ICLEI  
 Infiniti Medical  
 Instrumenta  
 International Antimony Association  
 International Federation for Medical and Biological Engineering  
 International Society of Doctors for Environment  
 Intramedic  
 Irradia AB  
 J & J  
 JE Laserservice AB  
 Karl Storz  
 KEN Hygiene Systems  
 Labrum  
 Laerdal Medical  
 Maquet Nordic AB  
 Martinsson Elektronik AB  
 Medcore AB  
 Medical market  
 Medicines and Healthcare products Regulatory Agency  
 Medicvent  
 Mediel AB Toshiba Mediel  
 Mediplast  
 Mediquipe  
 Medrad  
 Medtronic AB  
 Merivaara  
 Microsoft AB  
 Miele AB

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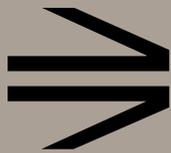
Milmedtek  
 Ministry of health, Slovenia  
 MMM 3M  
 Neovanta Medical AB  
 NHS  
 NHS innovation  
 NHS supply chain  
 Nimax  
 Nino Lab  
 Nordic Medcom AB  
 Obstecare  
 Olympus  
 Ortivus  
 Philips Healthcare  
 Plastics Europe  
 PO Medica  
 Pulsen Application AB  
 Quickels  
 Radiotherapy equipment Scandinavia AB  
 RTI Electronics AB  
 Salusa  
 Santax/Hawa-Medical  
 Scanex Medical Systems AB  
 Scanflex Medical AB  
 Scanmed AB  
 Secma  
 Sectra Sverige AB  
 Servicios Generales  
 Servizio Sanità pubblica  
 Siemens Healthcare  
 Smiths Medical Sverige AB  
 Sorin Group Scandinavia AB  
 Sunnex Equipment AB  
 Sustainable Procurement, Department of Health, UK  
 Swemac imaging  
 SVK Röntgenteknik Jeppsson AB  
 Synmed  
 TG Instrument AB  
 The Norwegian health regions cooperation  
 The Standing Committee of European Doctors (CPME)  
 Tieto Healthcare

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Toshiba Medical Systems Corporation  
Unomedical  
Uppsala University Hospital  
Varian  
Welch Allyn  
Vingmed  
VWR  
Västra Götalandsregionen  
Ökologischer Ärztenbund e.V.



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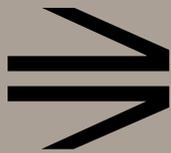
### APPENDIX III: PRIORITISATION LIST

<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
1	Anaesthesia equipment 1. Lung ventilators 2. Anaesthesia workstations	<p>1. Lung ventilators: A device providing automatic cycling used to assist/control alveolar ventilation by delivering an appropriate volume of gas to the respiratory airways. Respiratory gases are delivered to the patient's airway through a mouthpiece, mask or endotracheal tub.</p> <p>2. Anaesthesia working stations: A fully integrated general anaesthetic delivery device for oxygen, nitrous oxide, other medical gases, and anaesthetic agents. Its main components are the high, intermediate and low pressure gas delivery systems and the breathing circuit.</p>
2	Autoclaves, disinfectant equipment  1. Disinfectant equipment  2. Autoclaves/steriliser	<p>1. Disinfection is a process used to reduce the number of micro-organisms but not usually bacterial spores. The process does not necessarily kill or remove all micro-organisms, but reduces their number to a level which is not harmful to health.</p> <p>2. Autoclaves are used in sterilisation. The advantage of using an autoclave is that it can reach temperatures higher than boiling water alone, so it can kill not only bacteria but also bacterial spores, which tend to be resistant. Autoclaves are used in laboratories to ensure that items such as glassware and surgical equipment are sterile.</p>
3	CT (computed tomography)	<p>Computed tomography (CT) is a diagnostic procedure that uses special x-ray equipment to obtain cross-sectional pictures of the body. The CT computer displays these pictures as detailed images of organs, bones, and other tissues. Computed tomography is used to detect or confirm the presence of a tumour, to provide information about the size and</p>



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<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
		location of the tumour and whether it has spread, to guide a biopsy (the removal of cells or tissues for examination under a microscope), to help plan radiation therapy or surgery and to determine whether the cancer is responding to treatment.
4	Dialysis Equipment 1. Haemodialysis 2. Water purification system	<p>1. Haemodialysis equipment: A complete unit or comprising several connected units used in the process of cleansing a patient's blood from impurities caused through malfunction or failure of the kidneys. The principle of removing these impurities is by using a semi-permeable membrane.</p> <p>2. Water Purification system: A system made up of several units for the purpose of purifying water. Different methods may be used, e.g. filtration, deionisation, reverse osmosis or ultraviolet light. The units can be separately connected or combined as a single system.</p>
5	Diathermy equipment	Surgical diathermy apparatus: A device used for cutting and coagulating soft body tissue during surgery by the application of a high frequency current between an active and a neutral electrode, creating a heating effect that causes tissue destruction.
6	ECG equipment	The ECG is the most commonly performed heart test. This is because the ECG is a useful screening tool for a variety of heart abnormalities. You will lie on an examination table, and 10 electrodes (or leads) are attached to your arms, legs and chest. The electrodes detect the electrical impulses generated by your heart and transmit them to the ECG machine. The ECG machine produces a graph (the ECG trace) of those cardiac electrical impulses. The electrodes are then removed. The test takes less than 5 minutes to perform.
7	Endoscopic equipment 1. Laparoscopy 2. Gastroscopy	1. Laparoscopy is surgery that uses a thin, lighted tube inserted through a cut (incision) in the stomach to look at the abdominal organs or the female pelvic organs.



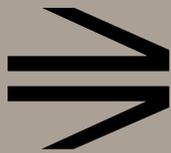
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<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
		<p>Laparoscopy is used to look for problems such as cysts, adhesions, fibroids, and infection. Tissue samples can be taken for biopsy through the tube (laparoscope).</p> <p>2. Gastroscopy is an examination of the inside of the oesophagus, stomach and duodenum. It is performed by using a thin, flexible fibre optic instrument passed through the mouth and allows the doctor to see whether there is any damage to the lining of the oesophagus or stomach, and whether there are any ulcers in the stomach or duodenum.</p>
8	Infusion pumps and syringe pumps	External infusion pumps are medical devices that deliver fluids, including nutrients and medications such as antibiotics, chemotherapy drugs and pain relievers, into a patient's body in controlled amounts. Many types of pump, including large volume, patient-controlled analgesia (PCA), elastomeric, syringe, enteral and insulin pumps, are used worldwide in healthcare facilities such as hospitals, and in the home.
9	Incubators for babies 1. Permanent incubators 2. Transport incubators	One of the most important elements in a newborn's survival is the infant's temperature regulation. Mammals have the advantage of being homeotherms, meaning that they are able to produce heat, allowing us to maintain a constant body temperature. However, homeothermy may be overwhelmed in cold or heat extremes. The newborn baby has all the capabilities of a mature homeotherm, but the range of environmental temperature over which an infant can operate successfully is severely restricted.
10	Intensive care equipment 1. Active humidifier	An active respiratory gas humidifier ensures that patients on mechanical ventilation are supplied with optimally conditioned respiratory gas. In active humidifying processes, moisture and heat is input to



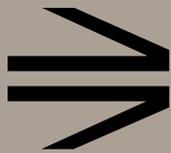
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<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
		<p>respiratory gas by an electrically powered humidifier. Performance data and safety-related requirements for active respiratory gas humidifiers are specified by standard ISO 8185. According to that standard, the minimum water content of inspired respiratory gas is approximately 33 mg/dm<sup>3</sup> and the maximum respiratory gas temperature is approximately 42°C.</p> <p>The aggregation of water in the gas produced by an active respiratory gas humidifier may be a suspension, or aerosol, which is produced by a nebuliser; or particulate water, output from an evaporator or bubble humidifier.</p>
11	Linear accelerators	<p>A linear accelerator (LINAC) is the device most commonly used for external beam radiation treatments for cancer patients. The linear accelerator is used to treat all body parts/organs. It delivers high-energy x-rays to the region of the patient's tumour. These x-ray treatments can be designed in such a way that they destroy the cancer cells while sparing the surrounding normal tissue.</p>
12	Medical freezers	<p>A low temperature freezer is a freezer which maintains a low temperature. Low temperature freezers are specially developed for laboratories and hospitals for the storage of sensitive material and usually used to store samples such as cells, embryos, semen in addition to volatile, flammable substances.</p>
13	Medical lighting 1. Surgical lighting	<p>A surgical light is to assist medical personnel during a surgical procedure by illuminating a local area or cavity of the patient. A combination of several surgical lights is often referred to as a "surgical light system".</p>
14	Monitoring equipment 1. Intensive and neonatal care	<p>Monitoring system: A unit for the collection, processing and often display of vital signs/patient data from one, or often more,</p>



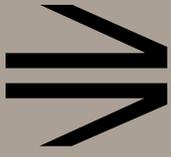
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<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
		bedside patient monitoring units. It produces visible and/or audible signals/alarms when adverse conditions are registered.
15	<b>MRI/MRT</b> 1. MR for extremities 2. MR for full body	An MRI (or magnetic resonance imaging) scan is a radiology technique that uses magnetism, radio waves and a computer to produce images of body structures. The MRI scanner is a tube surrounded by a giant circular magnet. The patient is placed on a moveable bed inserted into the magnet. The magnet creates a strong magnetic field that aligns the protons of hydrogen atoms, which are then exposed to a beam of radio waves. This spins the various protons of the body, and they produce a faint signal detected by the receiver portion of the MRI scanner. The receiver information is processed by a computer, and an image is produced.
16	<b>Patient warming systems</b> 1. Water borne blankets 2. Forced- air warming 3. Electric blankets	Unplanned hypothermia (a core temperature of less than 36°C) can negatively impact patients in many ways. Even mild hypothermia may contribute to complications such as surgical site infection (SSI), altered drug metabolism, impaired blood clotting, cardiovascular ischemia, prolonged recovery following surgery, and shivering. The use of forced air warming devices is for normalising patient temperature and reducing shivering. Forced-air warming is associated with reduced recovery time. In general warming systems reduce shivering and improve patient comfort and satisfaction.
17	<b>PET SPECT</b> 1. PET camera + CT 2. Gamma camera + CT 3. Gamma Camera 4. SPECT-gamma camera	1. PET-System: A diagnostic positron emission tomography (PET) imaging system designed exclusively to detect, record, quantify and analyse 511 keV photon emission patterns resulting from annihilation reactions produced during the decay of positron emitting radio pharm  3. Gamma camera: A diagnostic analogue



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<b>N R</b>	<b>PRODUCT</b>	<b>DESCRIPTION</b>
		or digital detector based planar (2-dimensional) nuclear medicine (NM) imaging system installed and used in only one location within an imaging facility or mobile/transportable imaging environment.
18	Surgical lasers 1. Argon laser 2. CO <sub>2</sub> laser	<p>Surgical lasers can make minute, precise incisions in hard-to-reach places and cause minimal blood loss.</p> <p>1. Many cancerous tumours are removed using a variety of laser instruments. CO<sub>2</sub> lasers are used today in neurosurgery, to remove brain tumours or alleviate pain. Laser instruments are also used to remove gallbladders and dissolve urinary stones. In addition, the CO<sub>2</sub> laser has become vitally important in treating laryngeal and pharyngeal cancers, which can be treated through the oesophagus using a laser rather than requiring an incision into the neck or throat.</p> <p>2. Argon laser with ionised argon as the active medium. Argon lasers are used for photocoagulation in ophthalmology.</p>
19	Ultrasound (diagnostic) 1. Mobile chargeable 2. Stationary	<p>Ultrasound Imaging: A portable or stationary ultrasound imaging system used to generate ultrasound pulses, e.g. frequencies greater than 20 kHz and to direct them to a target area of the human body, detect the ultrasound echoes, process the resulting information and produce</p> <p>A general purpose diagnostic ultrasound imaging system designed exclusively for use in a wide variety of both extracorporeal and/or intracorporeal (endosonography or endoscopic) body imaging procedures.</p>
20	X-ray equipment 1. General Diagnostic X-ray 2. Fluoroscopic X-ray 3. Mammography	<p>1. A general-purpose stationary diagnostic x-ray system is intended for use in a variety of routine planar x-ray imaging applications. It uses digital techniques for image capture, display and manipulation.</p>



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N R	PRODUCT	DESCRIPTION
		<p>2. A stationary general-purpose diagnostic fluoroscopic x-ray system that uses real-time digital techniques for image capture, display and manipulation and is specifically designed to be used in a variety of general-purpose applications requiring real-time</p> <p>3. A fixed installation in an imaging facility, or transportation van, x-ray system specifically designed to compress and image the breast. A digital mammography system (DMS) is used to record the absorption pattern of x-ray beams passed through the breast.</p>

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## APPENDIX V: THE RFI, REQUEST FOR INFORMATION

### MEDICAL ELECTRICAL EQUIPMENT RFI

#### Brief background information

The Swedish Environmental Management Council (Miljöstyrningsrådet (MSR)) develops criteria for sustainable procurement. We are now in the process of developing criteria for medical electrical equipment. We have also been appointed by the European Commission to develop criteria for the EU GPP Toolkit, so they will be available for **all EU public procurers** within healthcare.

For further information about the project, time schedule, important activities and meetings and participation, see the separate Project Document attached to the e-mail.

#### Why reply to this RFI?

By responding to this RFI you will be able to influence the upcoming criteria. The result of the RFI will be the basis for the criteria—in this way MSR will match the upcoming criteria with what the market can offer.

The work you put into this RFI will be useful for you later—because when the upcoming criteria are developed and used by the public procurers in healthcare, you will already have gathered the information! A benefit with the GPP criteria is that public procurement criteria are harmonised and in this way it will be easier for the suppliers to write their tender documents.

#### How to reply

You only need to reply to the questions relevant for your medical electrical equipment.

If you produce/sell a large number of equipment, we recommend choosing approximately six kinds of typical equipments in your assortment. Another suggestion would be to choose the three most frequently sold kinds of equipment and the three models with the best environmental profiles. If these are the same models, then add up the number to a total of six.

#### Contact

If you have any questions, you are more than welcome to contact Eva Dalenstam, [eva@msr.se](mailto:eva@msr.se), alt. +46 (0)8 700 66 95.



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### Due date

In order for us to be able to process your answers and be able to integrate them into our statistics to serve as a basis for the criteria, we would like to receive your answer at the latest by **29 July 2011**.

### Confidentiality agreement

We offer a **confidentiality agreement**, please contact Eva Dalenstam for this.

### THE RFI COMPRISES THE FOLLOWING EQUIPMENT:

Please tick the box/boxes according to what equipment you produce/sell:

1. MI Cyclotron
2. Cathlab
3. MRI
4. CT
5. PET and PET CT
6. X-ray equipment
7. Mammography
8. Ultrasound
9. IT and servers for medical equipment and medical systems
10. Incubators
11. Monitoring equipment, patient surveillance equipment
12. Autoclaves, disinfectant equipment
13. Linear accelerators
14. Lighting for surgery room
15. Infusion pumps
16. Surgery laser equipment
17. Medical freezers and refrigerators
18. Anaesthesia and intensive care equipment
19. Dialysis equipment and dialysis water supply equipment
20. Diathermy equipment
21. Endoscopy equipment, lacoscopy

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22. EKG equipment
23. Patient warming systems

**Please note that if you only sell one type of equipment, you do not need to specify equipment in the following questions.**

## QUESTIONS

### General questions

Your company's name:

Contact person at the company:

Type of company:

Producer, trademark owner  Wholesaler/retailer

What is your share of the EU market (%)?

How large a part of this share is sold to the public sector (%)?

Other comments:

### Environmental management, standards and labelling

Do you have environmental management systems according to ISO 14001 or EMAS?

Yes  No

Or do you work with environmental management systems in other ways?

Yes  No

Do you work according to the standard IEC 60601-1-9? Yes  No

Are any of your products environmentally labelled or energy labelled, for example with Energy Star or similar?

No  Yes, the following equipment: \_\_\_\_\_ are labelled with the following labels:

Do any of your products have an EPD, Environmental Product Declaration, or PEP, Product Environmental Profile?

No  Yes, the following equipment:

Other comments:

### LCA –life-cycle analysis

Have you performed any LCA for any of your equipment?

No  Yes, for the following equipment:

Can we take part of a result compilation of the LCA/s (i.e. not the whole LCA)?

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No  Yes, see attached document/s  Contact person, LCA:

Other comments:

LCC- life-cycle costing calculations

Do you work with LCC? Yes  No

Can we take part of your LCC tool? (i.e. the form and not the LCC calculation itself)?

No FORMCHECKBOX Yes, see attached document/s  Contact person, LCC:

Other comments:

Energy consumption

*Regarding 1.5 Energy Consumption, if you produce/sell several equipment, feel free to use the attached excel answering form if you do not want to use this answering form in word.*

What is the energy consumption of the equipment, in kW, during:

- Stand-by:
- The following treatments/examinations/use modes, please specify those most commonly used:
  - a) (describe type of use mode). Energy use: kW. Duration:
  - b) (describe type of use mode). Energy use: kW. Duration:
  - c) (describe type of use mode). Energy use: kW. Duration:
  - d) (describe type of use mode). Energy use: kW. Duration:
  - e) (describe type of use mode). Energy use: kW. Duration:

If there are many more important use modes, please describe these (see also excel form in order to fill in more use modes):

Or if you prefer to answer what the average energy consumption per month is (taking all different use modes into account), please answer here: kW/month

How is the energy consumption measured? Please describe:

Is there an equipment function so that it automatically turns off or it can be configured so that it automatically turns off after a certain time in stand-by when it is not used?

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Yes  No

Not suitable for this equipment because of patient safety aspects

Do you have a suggestion regarding how the energy consumption could be verified in a purchasing process?

Do IT-equipment for medical devices or medical systems and monitoring equipment fulfil the requirements of the latest PC ENERGY STAR<sup>®</sup> criteria?

Yes  No

Does the equipment have an economy/consumption meter? i.e., a device that measures the energy consumed. Yes  No

How much more energy efficient is your latest model compared to its predecessor or other models on the market (with the same performance)? (as a percentage)?

If your latest model is more energy efficient than your old model, what is the approximate price difference between these models (as a percentage)?

Other comments:

#### Heat generation

*Regarding 1.6 Heat Generation, if you produce/sell several kinds of equipment, feel free to use the attached excel answering form if you do not want to use this answering form in word.*

Does any of your equipment generate heat?

No  Yes, the following equipment:

Describe whether and how you work to reduce the energy consumption required to cool the heat generated from the equipment:

How much more energy efficient is your latest model compared to its predecessor or other models on the market, regarding energy efficient cooling systems?

What is the approximate price difference of your latest model compared to your old model (as a percentage)?

Other comments:

#### Chemicals in the equipment

*Regarding 1.7 Chemicals in the equipment, if you produce/sell several kinds of equipment, feel free to use the attached excel answering form if you do not want to use this answering form in word.*

What equipment already fulfils the RoHS requirements today? The following equipment:

The following equipment does not fulfil the RoHS requirements:

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Does any of your equipment contain any chemicals listed in the REACH candidate list?

Yes, the following equipment:                      No  Do not know

Does any of your equipment contain any of the following chemicals<sup>10</sup> (>1% in homogeneous material in those parts of the equipment where the chemicals exist)?

Phthalates DIDP, DINP, DNOP                      Yes  No  Do not know

Antimony trioxide                                      Yes  No  Do not know

Beryllium/beryllium oxide                          Yes  No  Do not know

Bisphenol A    Yes  No  Do not know

Arsenic trioxide                                        Yes  No  Do not know

Gallium arsenide                                      Yes  No  Do not know

Nickel/nickel trioxide                                Yes  No  Do not know

Nonyl phenoles/nonyl phenol ethoxylates                      Yes  No  Do not know

Medium chained chloroparaffins MCCP                          Yes  No  Do not know

Tetra bromo bisphenol A                            Yes  No  Do not know

Vanadium pentoxide                                 Yes  No  Do not know

Brominated flame retardants<sup>11</sup>                      Yes  No  Do not know

Do you have a suggestion regarding how chemicals content could be verified in a purchasing process?

<sup>10</sup> These chemicals were chosen according to a report produced by the Swedish Environmental Management Council – *Chemicals in electrical and electronic equipment*, where chemicals suggested for upcoming regulations and identified by companies as priority chemicals were prioritised. The report is available in Swedish, [www.msr.se/PageFiles/5027/MSR\\_2010\\_6.pdf](http://www.msr.se/PageFiles/5027/MSR_2010_6.pdf)

<sup>11</sup> Brominated flame retardants other than the ones regulated by RoHS and present in the REACH candidate list



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Describe what improvements (regarding the chemicals listed above) that have been made, in your latest model compared to its predecessor or other models on the market (with the same performance)?

Other comments:

Water consumption

*Regarding 1.8 Water consumption, if you produce/sell several kinds of equipment, feel free to use the attached excel answering form if you do not want to use this answering form in word.*

Does the equipment consume water?

No

Yes, the equipment consumes                    litres of water per treatment, please specify treatment 1:

If there are several different types of treatments/use modes, please specify:

The equipment consumes                    litres of water per treatment, please specify treatment 2:

The equipment consumes                    litres of water per treatment, please specify treatment 3:

The equipment consumes                    litres of water per treatment, please specify treatment 4:

The equipment consumes                    litres of water per treatment, please specify treatment 5:

How do you work to reduce the water consumption of the equipment?

How much have you reduced water consumption in your latest model compared to its predecessor or other similar models on the market?                    (as a percentage)

Special questions for dialysis equipment:

Does the water need to be heated?

No

Yes, the equipment consumes                    kW per litre of water.

The water purification unit uses approximately                    litres of fresh water per day (i.e. not recirculated water). If it varies, please specify an interval.

How do you work to reduce the consumption of energy and fresh water consumption?

How much have you reduced energy consumption and fresh water consumption in your latest model compared to its predecessor or other similar models on the market?                    (as a percentage)

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### Helium consumption

If helium is consumed by the equipment – are you working with reduced helium consumption? Yes  No

How much helium reduction is achieved in your latest model compared to its predecessor or other models on the market (with the same performance)?

### Extra questions for freezers and refrigerators

What refrigerants are used in the freezers and refrigerators? The following refrigerants \_\_\_\_\_ with the following GWP (Global warming potential) are used in the following equipment

### Origin and social/ethical questions

Is there a person in the company management responsible for CSR and monitoring compliance with social and ethical requirements?

Yes  Contact person: \_\_\_\_\_ No  Do not know

In which countries and cities is the equipment produced?

In the following countries and cities: \_\_\_\_\_ Do not know

In which countries do your suppliers produce the components for your equipment?

In the following countries and cities: \_\_\_\_\_ Do not know

### Gas consumption (for anaesthesia apparatus)

Is the apparatus equipped with a low-flow option? (For nitrous oxide etc.) Yes  No

Is the apparatus equipped with an on-demand valve? (For nitrous oxide etc.) Yes  No

### Recycling/waste management

Do you offer hospitals pick-up of old equipment?

Describe your work with waste management of the equipment, how is old equipment maintained?

Do you offer customer refurbishment and upgrading of old equipment (i.e. not switching old equipment to new equipment) Yes  No

Can you then offer the same guarantee as for new equipment? Yes  No

Can old refurbished equipment be made more energy efficient in the refurbishment process? Yes  No

Other comments:

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### Weight

Are you working with weight reduction of the equipment? Yes  No

How much weight reduction is achieved in your latest model compared to its predecessor or other models on the market (with the same performance)?

Question that should have been asked

MSR should have asked this question:

Then we would have answered this:

**Thank you very much for your participation!**

Best regards,

Eva Dalenstam, Project manager, SEMCo