PRACTICE Greenhealth

Suggested Environmental Questions for Electronic Medical Devices

The suggested environmental questions below may be used in the RFP/RFI or as part of the value analysis process. The questions cover electronic medical devices - anything that plugs in or has a battery. Some questions are signaling questions and suppliers may not be able to answer YES at this time (for example, EPEAT and ENERGY STAR).

Topic	#	Question	Preferred Response	Definition	Rationale
Resource Conservation	1.	Is this product EPEAT-registered? (Yes/No/NA) If yes, at what level (Bronze, Silver, Gold)?	Yes/NA	EPEAT does not currently apply to medical electronic equipment at this time.EPEAT, the Electronic Product Environmental Assessment Tool, is an open registry for greener electronics, which currently includes office equipment and televisions. Medical devices are not included in this scope. All of the criteria used in EPEAT are based on ANSI-approved public standards. Products are measured against both required and optional criteria. A product must meet all of the required criteria in its category to be added to the registry. It is then rated Bronze, Silver or Gold depending on how many of the optional criteria it meets. EPEAT currently covers PCs (desktops, laptops, workstations, thin client devices) and displays and in 2013 will expand to include televisions, and devices defined by ENERGY STAR as "Imaging Equipment"- including printers copiers, multi-functional devices, fax machines, digital duplicators and mailing machines.	EPEAT®-registered products meet a number of environmental criteria. From fewer toxicants in the product, to use of recycled content and design for easier recycling, EPEAT-registered products offer a reduced environmental impact across their lifecycles. EPEAT requires manufacturers of registered products to provide end of life takeback and responsible recycling. EPEAT's requirement that registered products meet the latest ENERGY STAR specifications means these products will consume less energy throughout their useful life. More at www.epeat.net

	2.	If applicable, is the product qualified to the latest version of ENERGY STAR? (Yes/No/NA)	Yes/NA	If Questions #1 is YES, then this question will also be YES. Medical devices are not currently covered by ENERGY STAR at this time but ENERGY STAR is working on establishing energy efficiency test methods for medical devices. ENERGY STAR is a joint program of the U.S. Environmental Protection Agency and the U.S. Department of Energy helping purchasers save money and protect the environment through energy efficient products and practices. ENERGY STAR covers a wide range of products; however, medical devices are currently not included. Therefore, a response of NA will be an acceptable answer for medical devices until a program is established.	This question applies to many electronic products, including office equipment; however medical devices are not covered by ENERGY STAR at this time. ENERGY STAR will consider new product categories when several factors are met, including standardized testing protocols for consumption and performance.
Resource Conservation	3	Does this product have instructions for users how to minimize environmental impact during installation, use, service and disposal/recycling? (Yes/No)	Yes	A user guide provides instructions on green performance management, including instructions how to minimize consumption of energy, water, gas, consumable materials/parts, emissions, etc. It may include recommendations on proper maintenance of the product, including which spare parts can be replaced. IEC 60601-1-9 outlines instructions manufactures should provide on minimizing environmental impact when applicable, including how to install, use and maintain equipment to minimize environmental impact, and how to minimize energy, water, consumables materials/parts emissions, during normal use, and information on the location of hazardous substances, radioactive sources and induced radioactive materials.(4.5.2) Information shall also be provided on proper disposal of the equipment at the end of life. (4.5.3)	Product materials shall be available either online, CD or paper format and shall provide guidance on how the product can maximize environmental performance to minimize impact. Educating users on how electronic equipment can be utilized to improve its green performance will support energy as well as other efficiencies while ensuring equipment does not impact clinical performance. Based on one device category, life cycle assessment data indicates that energy consumption during use accounts for about 75% of the life cycle environmental impact of MRI equipment.

Chemicals of Concern	4.	Does this product contain less than 1000 ppm halogenated organic flame retardants by weight of homogenous material? (Yes/No)	Yes	Halogenated organic flame retardants are intended to inhibit ignition and the spread of flames. Halogenated chemicals are chemicals that contain bromine, chlorine, fluorine or iodine bonded to a carbon atom. Homogeneous means uniform composition throughout, such as individual types of plastics or paper. Homogenous material, as defined by RoHS, is a unit that cannot be mechanically disjointed into single materials, or any material that is not mechanically divisible (disassembled, cut or ground) into separate material constituents. Mechanically disjointed means the materials can be, in principle, separated by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.[iv] Guidance for suppliers on testing is available.	Halogenated organic flame retardants and/or their breakdown products tend to be persistent bioaccumulative and toxic (PBT) in the environment. They are widely found in the environment and in humans with Americans having some of the highest levels of them in their bodies. Some halogenated organic flame retardants are carcinogenic. These compounds are used in foams (for furniture and mattresses), textiles, paints and coatings, electronics, and plastics in health care. Alternatives exist that reduce the concern for environmental and human health effects. The European Union has a ban on some brominated flame retardants. In Europe, the Restriction of Hazardous Substances Directive (RoHS) restricts the use of PBDE's and PBB's in electronic equipment.
	5	Is this product or its components free of intentionally added phthalates: DEHP, BBP, DnHP, DIDP, or DBP? (Yes/No) If no, please specify the phthalate(s)	Yes	Phthalates are esters of phthalic acid mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity). They are used primarily to soften polyvinyl chloride (PVC).	People can be exposed through the use of products containing these chemicals. In 2002, the FDA issued a Public Health Notification for PVC devices containing DEHP. DEHP is also listed as a carcinogen on the Prop 65 list. The National Research Council has also noted the importance of looking at cumulative exposure from multiple phthalates. These five phthalates are listed as reproductive toxicants by Prop 65. Di-2-ethyl hexyl phthalate (DEHP) CAS 117-81-7, Benzylbutylphthalate (BBP) CAS 85-68-7, Di-n-hexyl phthalate (DnHP) CAS 84-75-3, Di-isodecyl phthalate (DIDP) CAS 68515-49-1 or 26761-40-0, Dibutyl phthalate (DBP) CAS 84-74-2

	6	Is this product compliant with EU RoHS? (Yes/No)	Yes	The European Directive "RoHS" restricts the use of heavy metals, lead, mercury and hexavalent chromium, at no more than 1000 ppm, and cadmium at 100 ppm to reduce the environmental impacts of devices at the end of life. RoHS also restricts the use of two types of flame retardants (PBDE's and PBB's) in electronic equipment. RoHS applies to electronic medical products in July, 2014, and *In Vitro* Diagnostics beginning July, 2016.	Lead and mercury are potent neurotoxicants. Once released to the environment, they will persist. Depending on their form, lead and mercury can bioaccumulate. Hexavalent chromium is a known human carcinogen. Cadmium is an extremely toxic metal.[3] Lead accounts for most of the cases of pediatric heavy metal poisoning (Roberts 1999)[4]. Landfill studies show electronics are the major source of heavy metals in leachate, which can contaminate ground and surface water. Mercury vaporizes at room temperature and can expose workers and travel miles from the source of its release. Metals may enter the human body through food, water, air, or absorption through the skin. They can build up in the food web and become a significant health hazard. See Question #4 for the rationale about Halogenated Organic Flame Retardants PBDE's and PBB's
Chemicals of Concern	7	Is this product free of intentionally added Bisphenol A (BPA) or BPA derived plastics (such as polycarbonate plastic and resins)? (Yes/No)	Yes	Bis(4-hydroxyphenyl)propane, or Bisphenol A (BPA), is an organic compound used to make polycarbonate plastic, epoxy resins and other applications. Polycarbonate plastic is derived from BPA. Resin derived from BPA is used to line metal food containers and in thermal paper for impact printing purposes. Intentionally added means a substance is deliberately utilized in the production of the product.	Potential for oral, dermal or inhalation exposure during their intended use do not contain or release BPA (CAS 80-05-7) more than 10 ppm (0.6ppm for parts in contact with nutrition flow for babies). BPA is one of the highest volume chemicals produced worldwide. BPA is an endocrine disruptor and has been linked to many human health effects. It is known to leach out of polycarbonate plastics. [xi] The National Toxicology Program has some concern for the effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to Bisphenol A. There may be few alternatives for polycarbonate plastics.

Chemicals of Concern	8	What is the total amount of mercury (in milligrams), including in light sources? (Total number of milligrams)	Lowest Number (mg)	Lights may contain mercury and the amounts vary depending on manufacturer and type of bulb. In some cases, such as with Compact Fluorescent Lights (CFLs), which contain mercury AND help achieve energy savings, it is important to seek the lowest levels of mercury.	Mercury is a potent neurotoxicant that can affect the brain, spinal cord, and peripheral nerves. It is also toxic to the kidneys. Mercury can be released from lamps through breakage during disposal, repair or recycling. Efforts in health care are intended to reduce exposure to patients and staff, address workplace safety, and safely handle products at the end of life. Mercury in some forms is also persistent bioaccumulative and toxic (PBT).
	9	Is this product free of carcinogens and reproductive toxicants above Safe Harbor levels, as listed under the CA Safe Drinking Water and Toxic Enforcement Act of 1986, Proposition 65? (Yes/No)	Yes	California's Prop 65, The Safe Drinking Water and Toxic Enforcement Act, enacted in 1986, requires the state to publish a list of chemicals known to cause cancer or reproductive harm. Prop 65 applies to suppliers who sell products in the state if their products exceed safe harbor levels established in Prop 65. Safe harbor levels establish thresholds for no significant risk levels (NSRLs) for carcinogens and maximum allowable dose levels (MADLs) for chemicals that cause reproductive toxicity.	The California Proposition 65 list is an authoritative government list of carcinogens *and* reproductive toxicants that health care facilities may wish to avoid. All suppliers who do business in California must comply with this law. As such, this law already applies to many suppliers in the health care sector. Since this list is updated at least once a year, suppliers must provide up-to-date information for procurement contracts.
	10	For this product, have Tier 1 suppliers been asked in writing to disclose the full materials and chemical ingredients to 0.1% by weight? (Yes/No/NA)	Yes/NA	A Tier 1 supplier is the immediate or primary set of vendors directly used by a company, and tier 2 is a vendor to Tier 1. This question is only asking if manufacturers ask suppliers for this information in writing. It does not require this information to be disclosed.	There are over 75,000 registered chemicals and many have not been tested for human health impacts. This shifts the burden to purchasers and users to understand the chemicals of concern in order to make informed decisions. Full material disclosure helps address new ingredient concerns or regulations in a timely manner when products are already in use and improve required response to reduce the potential for harm. Suppliers who ask for full material and chemical ingredients will enable more informed decision-making and expeditious action. For more information, see full materials disclosure example, http://greenchemistryandcommerce.org/downloads/SeagatesApproachtoProductEnvironmentalCompliance.pdf .

	11	Is this product free of PVC including wiring and cabling? (Yes/No)	Yes	Polyvinyl chloride (PVC) shall be defined as a plastic polymer used in a wide array of products. It is the third most widely produced plastic. Intentionally added means a substance is deliberately added in the production of the product. PVC has commonly been used as a protective sheath around cables and wiring, and PVC is one of three acceptable materials in UL standard 817 for cabling and wiring. However, many companies are actively moving to alternatives.	Polyvinyl chloride (PVC) is a versatile, high-volume, synthetic polymer with many different formulations and configurations. A number of health and environmental risks are inherent in the life cycle of this plastic. Manufacture of PVC requires hazardous chemical inputs. The manufacture and incineration of PVC can generate dioxins, furans, and other hazardous chlorinated byproducts. PVC requires additives to impart properties like flexibility and heat resistance. Some of these additives pose risks. There are also concerns about the inappropriate incineration of end-of-life electronics equipment via informal recycling carried out at temperatures below 800°C. This has led to a growing concern that these materials pose risks to health and the environment (releasing dioxins and other chemicals, for instance).[5] In general, alternatives are widely available. There are some cases – high current, high temperature applications – where alternatives are less available. [6] (This question would not pertain to refurbished equipment, which would be environmentally preferable.)
End of Life	12	Is this product a part of a manufacturer-run or manufacturer-sponsored Take Back Program? (Yes/No) If yes, does the program use e-Steward certified electronics recyclers? (Yes/No)	Yes/Yes	A Take Back Program is part of an environmental protection strategy to decrease the total environmental impact of a product, by making the manufacturer of the product responsible for the entire life-cycle of the product and especially for the take-back, recycling and final disposal of the product. Suppliers who take back electronic products can have them reused through a refurbisher, the most preferable, or recycle them responsibly using an e-Stewards certified recycler (adhere to the highest standard of environmental responsibility and worker protection). See www.e-Stewards.org/find-a-recycler/.	Take-back programs create incentives for companies to redesign their products to minimize waste management costs, by designing their products to contain safer materials (so they do not need to be managed separately) or designing products that are easier to recycle and reuse (so recycling becomes more profitable) e-Stewards prohibits toxic waste from being disposed of in solid waste landfills and incinerators, prohibits the use of prison labor in the recycling of toxic electronics, which often have sensitive data embedded, and requires full compliance with existing international hazardous waste treaties for exports and imports of electronics, and specifically prohibits the export of hazardous waste from developed to developing countries. We consider this standard to be more protective of worker health and environmentally protective, and more rigorous than other standards.

Packaging	13	Does this product's primary package contain at least 10% postconsumer recycled content? (Yes/No)	Yes	The primary packaging surrounds the product. For example the paper wrap surrounding a roll of toilet paper is primary packaging. (Secondary packaging surrounds a group of products, such as the box containing rolls of toilet paper.) Postconsumer recycled content material is a material or finished product that has served its intended use and has been diverted or recovered from waste destined for disposal, having completed its life as a consumer item.[7] Postconsumer recycled content is the material collected from recycling programs and is calculated as a percentage of the total weight of the product.	Buying recycled-content products ensures that the materials collected in recycling programs will be used again in the manufacture of new products. According to EPA, recommending postconsumer recycled content levels for items will have the most positive impact on reducing the amount of solid waste requiring disposal. Purchasers should prefer products with the highest postconsumer recycled content that also meet other considerations. Use of postconsumer recycled content is fundamental to closing the loop in the recycling process, using fewer natural resources, and based on EPA's ReCon Tool, can reduce greenhouse gas emissions. There are exceptions to the use of postconsumer recycled content in sterile barrier packaging (ISO 11607-1).
	14	Is this product packaged without polystyrene and polyvinyl chloride? (Yes/No)	Yes	Polystyrene (CAS 9003-53-6) is a plastic polymer from the monomer styrene. It comes in many forms: sheet, expanded or extruded foam, or as oriented polystyrene. What is commonly known as Styrofoam™ refers only to the extruded form of polystyrene. Packaging refers to all materials (primary, secondary, etc) used to transport and protect a product from damage. Alternatives to polystyrene packaging are available. Polyvinyl chloride (PVC) shall be defined as a plastic polymer used in a wide array of products. It is the third most widely produced plastic. Intentionally added means a substance is deliberately added in the production of the product.	Also referred to as 'PS' with the SPI (Society of the Plastics Industry) resin code 6, polystyrene is difficult for hospitals to recycle and there are alternatives. Polystyrene is made with styrene.The International Agency for Research on Cancer (IARC) classifies styrene as a possible carcinogen.[1] Foam blowing agents (called hydrochlorofluorocarbons, HCFCs) used to make polystyrene foam are compounds that have an ozone depletion potential [2]. Production and incineration of PVC releases dioxins and other harmful chemicals. Dioxins are widely distributed throughout the environment in low concentrations and are persistent, bioaccumulative and toxic (PBT). Dioxins are potent toxicants with many health impacts even at low exposure levels.

[1] U.S. Environmental Protection Agency, "Air Toxics- Styrene," http://www.epa.gov/ttnatw01/hlthef/styrene.html, website viewed June 2011

[2] Phaseout of HCFCs, Ozone Layer Depletion, U.S. EPA, http://www.epa.gov/ozone/title6/phaseout/classtwo.html viewed September 2011

[3] RoHS Producer Support Booklet, National Measurement Office, 2010, pg 6, http://www.bis.gov.uk/assets/bispartners/nmo/docs/rohs/support-literature/producer-

[4] U.S. Environmental Protection Agency, “Air Toxics- Styrene,” http://www.epa.gov/ttnatw01/hlthef/styrene.html, website viewed June 2011

[5] Case Study, "An alternative to PVC in wires and cables. A kind of plastic completely free from halogens, BFR´s (brominated flame retardants), PVC and plasticizers," Subsport.eu, http://www.subsport.eu/case-stories/084-en. Accessed July 2012

[6] Mark Rossi email July 2012

[7] U.S. Environmental Protection Agency, “Wastes-Resource Conservation – Comprehensive Procurement Agency,

[8] Vandeberg, L.N., and others, “Human Exposure to Bisphenol A (BPA), *Reproductive Toxicology* (August-September 2007) 139-77.

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