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Elements of a Responsible Product Life Cycle

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Elements of a Responsible Product Life Cycle

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Contents

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Elements of a Responsible Product Life Cycle

1 Background

Over recent decades, several key technical trends have shaped the current state of product safety, performance, and clinical efficacy in today's healthcare setting. Currently, the medical device industry is facing an emergent trend that will add new considerations in the assessment of market acceptability of medical products and services. Based on historical practices and projected future demands for safe medical products and services, the medical device industry must assess and reconfigure its guidelines to include additional safety and efficacy precautions that protect the patient, healthcare workers, and the communities they serve by incorporating an environmental health perspective.

Technology breakthroughs in plastics formulation and injection and blow molding during the mid-1960s helped reduce the incidence of infection transmission, allowing the medical device industry to shift much of the clinical market away from reusable devices requiring sterilization between uses to single-use disposable devices. There is no question that infections in clinical settings have declined dramatically as a result this change, but the transition has come at the cost of hundreds of tons of fossil fuel-based devices posing a disposal burden on the healthcare provider.

More recently, during the mid-1980s, the high incidence of HIV and AIDS drove the healthcare industry to adopt a more rigorous approach to protecting healthcare workers from pathogen exposure and injury. Occupational risks to healthcare workers continued to grow with the increased use and handling of chemotherapies, sterilizing, cleaning, and other chemical agents, as well as with the emergence of staph-resistant "super bugs," such as Methicillin-resistant *Staphylococcus Aureus* (MRSA). The medical device industry has continually worked to address these challenges with an array of product enhancements designed to protect both the patient and the healthcare worker from bloodborne pathogens and other occupational exposures.

A third safety issue emerged in the 1990s with a new understanding of latex allergies for healthcare workers and patients. Between 1988 and 1992, the FDA received more than 1000 reports of latex allergic reactions; 15 patient deaths occurred as a result. Reactions to natural rubber latex range from mild dermatitis to life-threatening anaphylactic shock. Following the CDC's recommended Standard Precautions, the use of natural rubber latex was pervasive across the medical device industry with sources of supply of variable quality. The industry responded with alacrity both by developing improved processes to reduce the allergenic potential of natural rubber latex and by developing synthetic alternatives. Today, there are latex-free alternatives for nearly every mainstream medical device, demonstrating the industry's ability to maneuver when critical safety issues arise related to chemicals and materials.

Explosive population growth and massive industrialization and development over the last 100 years have led to a new global crisis that will pose a new product safety and performance challenge to the medical device industry. The natural resources that humans depend on for life are being depleted at a growing rate. Science has begun to link exposure to a myriad of common chemicals to health impacts in humans, and the scientific community has come to a consensus that global climate change will have serious and nearly immediate impacts for human health and the environment (Costello, 2009). The World Health Organization (WHO) recognizes these risks (WHO, 2002) and estimates the direct damage costs to health at between $2-4 billion USD per year by 2030 (WHO, 2012).

Across the globe, medical institutions are acknowledging the inextricable link between healthy people and a healthy environment. As healthcare institutions align themselves more closely with not only treating sickness but also protecting and enhancing wellness, there will be a definitive call for the medical device industry to consider the environmental, health, and safety implications of communities and the natural environment, in addition to patients and healthcare workers.

2 Value Proposition

Sustainable Development has been described as, "Providing for the needs of today, while ensuring that future generations have the ability to meet their own needs" (Brundtland Commission, 1987). It has also been described as the “Triple Bottom Line,” where three resources intersect: 1) Economic; 2) Environmental; and 3) Social. Where these priorities overlap is where businesses will thrive by providing products that serve customers, reduce costs, and offer enhanced environmental health and safety benefits. There are numerous global drivers for sustainability within the medical supplier industry.

- **Countries require it:** Compliance with Environmental Health and Safety (EHS) product and packaging regulations has become a global legislative requirement, where certain materials are being banned in some products, such as lead, mercury, cadmium, and chromium in electronic medical equipment/devices. Nonconformance with requirements, such as REACH and RoHs, eliminates products from being sold in some global markets, for example, the European Union, and could deny patients life-saving and life-sustaining products.

- **Customers demand it:** Based on a customer survey conducted by Johnson & Johnson in 2012, 54 % of customers reported that product environmental attributes were important in their purchasing decisions, and 40 % indicated that they would be including such attributes in future Requests for Proposal. In the same survey, 35 % of the organizations said they have switched suppliers in order to obtain more sustainable products. As an example, Kaiser Permanente, which purchases $1-2 billion of medical products per year, has developed a Sustainability Scorecard that rates the EHS performance of products and is making purchasing decisions based on this evaluation.

- **Investors reward it:** Over the past decade, investor demand has resulted in increased transparency around corporate sustainability. Companies such as Goldman Sachs (2011) are now routinely evaluating ESG (Environmental-Social-Governance) issues for companies in their portfolios and making recommendations to investors based on these assessments. Resource efficiency—using less energy, water, and producing less waste in generating a unit of revenue—is becoming a reliable indicator of improved economic performance and is one that investment managers will be keeping a keen eye on in the future (Heyns, 2012). Assets in sustainable managed funds now exceed $5 trillion, and publicly owned companies are being recognized for their focus on corporate social responsibility (CSR) through inclusion in elite funds, such as the Dow Jones Sustainability Index, Global Reporting Initiative (GRI), Carbon Disclosure Project, and FSTE4Good Index, based on the companies’ sustainability report, governance, and transparency, which add both economic and reputational value.

- **Employees desire it:** Studies show that sustainability attracts and retains employees, which helps maintain critical talent within an organization. A 2012 Net Impact survey of 1,726 people found that respondents would be willing to take a 15 % pay cut to work for an organization committed to CSR (35 %), to have a job that makes a social or environmental impact (45 %), and to work for an organization whose values are like my own (58 %). Nearly 65 % of students and 51 % of the current workforce said that “making the world a better place” was very important or essential in the ideal job.

The healthcare industry is committed to promoting programs that encourage and support healthy practices and lifestyles and providing products and services to protect and restore health, alleviate pain, and extend life. There is a clear link between healthy people and a healthy community and planet,

because both are needed for the sustainable growth of companies (Economic), promotion of a healthy society (Society), and protection of the natural environment (Environment).

3 Social

Medical devices help to meet a significant social need by providing healthcare options that improve and save lives. However, to create and deliver a responsible medical device supply chain, there are also elements of social impact that should be given consideration. There are many stakeholders defining and shaping which social elements are in scope and how companies should measure and report impact, including the Global Reporting Initiative (GRI), Ethical Trade Initiative (ETI), and Sustainability Accounting Standards Board (SASB). Within these initiatives, there are common areas of impact that are essential to consider in order to create a responsible medical device lifecycle:

- **Product safety:** Consistently developing and delivering safe and high quality medical devices is critical to ensuring patient outcomes.

- **Employment and Supplier Labor Practices:** According to the ETI internationally recognized code of labor practice, employers should adopt specific principles regarding fair labor practices and human rights. Companies should also have a governance process in place to ensure suppliers conform to the same. These principles include the ability to freely choose employment, access to safe and hygienic working conditions, working hours that are not excessive and provide a living wage, an absence of discrimination or inhumane treatment, and no use of child labor.

- **Raw Material Sourcing:** Recent efforts have shown an increased demand for supply chain transparency to measure and disclose the impact of medical device raw materials sourcing. For example, in recognition of the link between the global minerals trade and the financing of armed groups in the Democratic Republic of Congo (DRC) region, the United States Securities and Exchange Commission (SEC) adopted a final rule (Rule 13(p)-1) requiring SEC-reporting companies that manufacture or contract to manufacture products that contain “conflict minerals” to conduct due diligence on the origin, source, and chain of custody of such minerals and provide specialized disclosure regarding the findings of such diligence. The SEC currently defines “conflict minerals” to include tin, tungsten, tantalum, and gold (Securities and Exchange Commission, 2013). In another example, from the United Kingdom, DEFRA has developed a resource scarcity action plan to address the growing need for access to rare earth metals used in specialized products, including medical devices (DEFRA, 2012).

- **Affordable Access:** While medical devices serve a social need by delivering healthcare outcomes, there is a need for continued innovation to address current and future unmet needs. While the pharmaceutical industry has had an Access to Medicines initiative and ranking system in place, the medical device industry has not coordinated any efforts around affordable access to devices. Recently, Business for Social Responsibility released, “Guiding Principles on Access to Healthcare,” with multiple healthcare CEO endorsements in order to set a framework for addressing five core areas of affordable access: collaboration, research & development, expanding availability of healthcare services, developing health systems resources, and respecting human rights.

4 Environmentally Preferable Product Design Categories

4.1 Waste

Today’s U.S. hospitals generate an estimated 7,000 tons of waste daily. According to the World Health Organization, 80 % of that waste is nonhazardous, and the remaining 20 % is considered hazardous material that may be infectious, toxic, or radioactive. The healthcare industry spends $10 billion annually in disposal costs (AHA, n.d.). Careful management, including segregation of nonhazardous material from hazardous materials, can save 40-70 % on disposal costs (Association of Bay Area Governments, 2003).

Only 11-14 % of electronic waste is being recycled today in the United States (E-Stewards, 2010). Between 70-80 % of the electronic items recyclers receive is being sent to less developed countries and burned in piles to retrieve the metals, thus exposing people and the environment to toxins (Brown, 2010). Careful selection of recyclers or alternate repair/reuse programs are available through nonprofit organizations for equipment and electronics that no longer have a life in their current facility.

An estimated 1.8 million pounds of plastics are used in hospitals each day (American Plastics Council, 1999). By recycling only 1 % of plastics, greenhouse gas emissions could be reduced by more than 10 metric tons of CO^2 equivalents per day as a result of reducing the amount of virgin polymer needed (EPA). This is equivalent to more than 23 barrels of oil per day, or the emissions from more than 1,000 gallons of gasoline per day (EPA, 2010).

"Red Bag" reduction by careful segregation can provide substantial savings. Recommendations by hospitals engaged in reduction programs include training and waste education, setting up formalized reduction programs, engaging in recycling programs, displaying reminder posters at collections sites, engaging in single-use device reprocessing, recycling sharps or implementing a reusable sharps container program, and utilizing fluid management systems in operating rooms, to name a few.

- **Minimizing Packaging:** Suppliers are finding new ways to maintain product sterility and integrity, while also minimizing the amount of overwrap, internal, and external packaging. Packaging reduction may include the use of reusable toters, recyclable packaging materials, ease of unpacking medical devices and supplies, and more targeted apportionment/sizing of product in individual packaging. Opportunities may also exist with packaging take-back programs designed to eliminate the waste burden on end users. A recycling program should analyze packaging to understand the proper segregation needs of the recycler to maximize efforts and minimize costs.

- **Product Designed for 3 Rs: Reduce, Reuse, Recycle:** Suppliers are beginning to consider mechanisms to formulate and design their devices, supplies, and equipment in such a way that they can be more easily disassembled; are more durable or reusable; are able to be safely cleaned, sterilized, and repackaged for reuse; or can be readily recycled in communities or through special manufacturer take-back programs. The Health Care Plastics Recycling Council has developed design guidelines to provide considerations regarding plastic materials and device design with recycling in mind. Consideration should be given to the way product end-of-life is managed, as well as the impact and cost of the use of an item with each product selected.

4.2 Materials

Today's medical device, supply, and equipment manufacturers use a myriad of materials in the design and production of their products. The composition of medical products is highly complex and involves determining appropriate biocompatibility for devices that come into contact with patient tissue, material integrity for devices or equipment that must be continually cleaned, sterilized and reused, and, of course—product quality and safety. Product packaging is also a complex science and requires maintaining product integrity and sterility during transportation, storage, and use. Product manufacturing can also be highly tailored to the use of certain materials or chemical components, and reformulation can require investment in new machinery and equipment to produce redesigned products and equipment. Suppliers are identifying new strategies to rethink the use of certain chemicals and materials of concern, and redesigning to incorporate the use of more environmentally preferable constituents. Sustainability strategies include the following:

- **Avoiding Chemicals of Concern:** Scientific data continues to emerge that suggests that the extraction, production, use, and disposal of certain materials in medical devices, supplies, and equipment can expose people to unsafe levels of chemicals that can negatively impact their health. Some suppliers have established criteria for the development of more sustainable products in various categories, including materials, packaging, energy, waste, water, social, and innovation. Whether impacting worker or community health in the extraction or manufacturing

process, impacting healthcare staff or patient safety in the clinical environment, or impacting frontline employees or the community in the disposal process, suppliers are looking for ways to reduce the use of chemicals of concern across their product portfolios. Efforts include targeting certain priority chemicals or materials for elimination in product lines. The list in review from the EPA includes *bisphenol A*, eight different *phthalates*, and *polybrominated diphenyl ethers*. Latex, mercury, PVC, DEHP, and brominated flame retardants are some of the chemicals or materials that are under evaluation or have been eliminated by suppliers.

- **Incorporating Environmentally Preferable Materials:** Environmentally preferable materials are those that have less impact on the environment and human health during extraction, processing, manufacturing, delivery, use, and at product end-of-life. Strategies include the use of life cycle analysis to assess and reformulate based on the use of alternative resources, methods, and processing to create not only the least environmental burden, but the greatest positive environmental impact. Exploration of recycled content, biodegradability, and recyclability are just a few examples. Manufacturers continue to explore alternatives that will meet stringent quality and safety standards, while reducing environmental impact; for example the use of more sustainable packaging materials such as those derived from certified forests and/or made from recycled paper (more than 30 % post consumer content).

- **Life Cycle Considerations**: Consecutive and interlinked stages of a product and packaging system must be considered, including raw material acquisition or generation from natural resources, raw material manufacturing, product manufacturing, distribution at all stages, storage, product use, and maintenance to end of life.

4.3 Energy

The bulk of energy used by the healthcare supplier and manufacturing sector, as well as healthcare providers, is petroleum-based. Burning fossil fuels to produce energy and the resulting air emissions have been associated with a myriad of public health impacts, including increased rates of respiratory and cardiovascular disease, asthma, and lung cancer, as well as acid rain, mercury emissions, and deposition of other heavy metals and particulate matter. Increasingly, medical device and equipment suppliers are exploring ways to reduce the energy use of their manufacturing operations, as well as ways to reduce the energy use of their equipment. Sustainability considerations fall into two broad categories:

a) **Manufacturing and Operations:** Suppliers are being asked to take steps to reduce greenhouse gas emissions (GHG), report GHGs and climate change strategy to the Carbon Disclosure Project (CDP) and other third parties, purchase EPEAT-registered electronic products for internal use, purchase Energy Star-rated electronic products for internal use, and manage distribution and transportation using EPA SmartWay Partners.

   Alternative and renewable energy systems can help lead to lower environmental impacts of a product.

b) **Energy Intensity of a Product:** There is nearly universal demand for equipment that requires less energy use. Considerations include both the in-use electrical energy consumption of a product and the continuous (or "standby") mode of electrical energy consumption. Suppliers are offering a host of energy-efficient innovations, including better equipment, stand-by or sleep modes, intermittent operating cycles, and reduced plug load. The healthcare sector is also exploring the feasibility of offering a third-party certification mechanism for the energy performance of medical equipment, such as EPA's EnergyStar label.

4.4 Water

Water resources are critical to the health of our communities and the balanced ecosystem of our planet. Commercial and institutional public water use is the second largest in the United States, representing 17 % of the overall water usage (EPA, 2013). Seven percent of the commercial and institutional total is

attributed to use in hospital and other healthcare facilities (Dziegielewski et al., 2000). The functions that utilize the most water in the hospital are sanitary (40 %), building cooling and heating (13 %), steam sterilizers (10 %), and laundry (10 %) (EBMUD, 2003).

Two of the four main actionable areas of opportunity highlighted by the EPA through their WaterSense program as having an impact on the management of medical devices include the recommendation to increase the water efficiency of fixtures, equipment, systems, and processes, as well as educating employees and occupants about water efficiency to encourage water-saving behaviors (EPA, 2012).

Medical suppliers are also being challenged to think about how they can provide complex medical equipment that meets patient diagnostic, safety, care, and infection control standards, while also using less water. Many hospitals are also stating a preference for medical equipment, devices, and supplies that require less water use.

4.5 Air Quality

According to the EPA, indoor air pollution poses high risks to human health, especially sensitive populations, and has ranked air quality among the top four environmental risks in relative risk reports. Chemicals and compounds contributing to indoor air pollution include organic compounds emitted from building materials, commercial cleaning products, asbestos containing insulation, cabinetry or furniture made from certain pressed wood products, and pesticides. Studies show the average American spends approximately 90 percent of their time indoors, and many do not realize that indoor air pollutants can pose the same risks as outdoor air contaminants.

Building materials, furnishings, cleaning chemicals, and other products that emit volatile organic compounds (VOCs) can affect indoor air quality. These compounds can trigger asthma attacks in sensitive populations. According to one study, occupational exposures, particularly among nurses, account for a substantial proportion of adult asthma incidence (Kogevinas et al., 2007). Commercial buildings, such as hospitals, have many design tools and resources available to guide strategies, including the use of efficient ventilation systems, to support healthy indoor air quality objectives. For example, there are prerequisites in LEED for Healthcare that outline ways to minimize indoor air pollution citing California's Department of Public Health Standard Method for Testing and Evaluating VOC Emissions, and several organizations will test and certify compliance with these protocols. Outdoor air quality requirements for products used outdoors can meet standards by the South Coast Air Quality Management District.

4.6 Standardization of Environmentally Preferable Attributes

As global industries shift to integrate more environmentally preferable attributes into product and service lines, it is increasingly important to be able to validate and verify those environmental claims through the use of standardized assessment tools that enable the benchmarking of claims. Manufacturers may use different internal standards and methodologies to measure and track progress toward their corporate and product sustainability achievements, but there remains a need for a universal standard or set of standards that can guide the industry and demonstrate to purchasers the validity of product/service sustainability claims. This standard needs to be comprehensive, and utilize transparent, objective, and quantifiable assessment methods and criteria that characterize the entire life cycle cost, including ecological impact of the delivery and maintenance of a product and its intended (specified) clinical performance. The standard should also include a reporting and marking scheme to communicate clearly to the end user.

Many industries have already begun to develop standards (or revise existing standards) to incorporate environmentally preferable attributes. AAMI is a recognized leader in developing Standards and Technical Information Reports for the medical device industry. The AAMI Sustainability Ad Hoc Committee has been created to explore and identify a set of deliverables that will drive environmentally sustainable design, production, use, and disposal of medical devices across the industry in a consistent, standardized way—benefiting both the medical device manufacturers and the healthcare purchasers who utilize these products to provide care and save lives.

5 Economic

In addressing economic information, this White Paper's focus is on the relationship and impacts of economic decisions on the organization, stakeholders, and communities in which the manufacturer operates. The intent is to recognize how the manufacturer uses financial resources to influence sustainable practices throughout the organization and among organizations of their stakeholders. Economic criteria address the cost-effectiveness of savings from other sustainable practices, including energy reduction and reuse of raw materials, and the cost benefit of the risk reductions associated in sustainable practices. For example, energy efficiency, waste reduction, and efficient supply chain management (internal and external) could lead to economic benefits.

6 Acronyms

CDP	Carbon Disclosure Project
CSR	Corporate Social Responsibility
EHS	Environmental Health and Safety
EPA	Environmental Protection Agency
EPEAT	Electronic Product Environmental Assessment Tool
ESG	Environmental-Social-Governance
ETI	Ethical Trade Initiative
GHG	Greenhouse Gas Emissions
GRI	Global Reporting Initiative
OSHA	Occupational Safety and Health Administration
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances (European Community regulation)
RoHS	Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (European Union Directive)
SASB	Sustainability Accounting Standards Board
VOC	Volatile Organic Compounds
WEEE	Waste Electrical and Electronic Equipment (European Community Directive**)**

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ISO 14006, *Environmental management systems -- Guidelines for incorporating ecodesign*

ISO 14020, *Environmental labels and declarations – General Principles*

ISO 14021, *Environmental labels and declarations – Self-declared environmental claims (Type II environmental labeling)*

ISO 14024, *Environmental labels and declarations – Type I environmental labeling – Principles and procedures*

ISO 14025, *Environmental labels and declarations – Type III environmental declarations – Principles and procedures*

ISO 14040, *Environmental management – Life cycle assessment – Principles and framework*

ISO 14044, *Environmental management – Life cycle assessment – Requirements and guidelines*

ISO 17422, *Plastics -- Environmental aspects -- General guidelines for their inclusion in standards*

ISO 18601, *Packaging and the environment -- General requirements for the use of ISO standards in the field of packaging and the environment*

ISO 18602, *Packaging and the environment -- Optimization of the packaging system*

ISO 18603, *Packaging and the environment – Reuse*

ISO 18604*, Packaging and the environment -- Material recycling*

ISO 18605*, Packaging and the environment -- Energy recovery*

ISO 18606, *Packaging and the environment -- Organic recycling*

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ISO/TR 24699, *Rubber and rubber products -- Environmental aspects -- General guidelines for their inclusion in standards*

ISO 26000, *Guidance for social responsibility*

ISO 50001, *Energy management systems*

7.2 UL Standards

UL Sustainability Standards:
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UL 880: Sustainability for Manufacturing Organizations:
http://www.ul.com/global/eng/pages/offerings/businesses/environment/services/sq/enterprisestandards/UL880/index.jsp

UL Certified Environmental Product Declarations Badge (certifications based on ISO standards):
http://www.ul.com/global/eng/pages/solutions/services/finder/detail/index.jsp?cpath=/global/eng/pages/solutions/services/finder/detail/data/121-environmental-product-declarations.xml

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Basel Action Network e-Steward Enterprise: http://e-stewards.org/

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REACH: http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm

RoHS: http://ec.europa.eu/environment/waste/rohs_eee/

Sustainability Accounting Standards Board: http://www.sasb.org/

Sustainable Packaging Coalition: http://www.sustainablepackaging.org/

US EPA Design for the Environment Program: http://www.epa.gov/dfe/

WEEE: http://ec.europa.eu/environment/waste/weee/index_en.htm

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