

Technical Information Report

AAMI TIR65:2015

Sustainability of medical
devices—Elements of a
responsible product life
cycle

Sustainability of medical devices—Elements of a responsible product life cycle

Approved 4 November 2015 by
Association for the Advancement of Medical Instrumentation

Abstract: Highlights sustainability considerations during the product design and manufacturing, acquisition and use, and end of life of medical devices, taking into account the life cycle impacts of the product.

Keywords: economic, environmental, manufacturer, material, social, supply, use

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Glossary of equivalent standards

International Standards or Technical Reports adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation Sustainability Committee

This Technical Information Report was developed by the AAMI Sustainability Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Sustainability Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this Technical Information Report does not constitute endorsement by the federal government or any of its agencies.

Introduction

The health care industry is committed to promoting programs that encourage and support healthy practices and lifestyles, and to providing products and services for detecting, preventing, monitoring, treating, or alleviating illness, injury, or disability. Across the globe, medical institutions are acknowledging the clear link between healthy people and a healthy community and planet, because each is needed for the sustainable growth of economies, promotion of a healthy society, and protection of the natural environment. As health care institutions align themselves more closely with not only treating sickness but also protecting and enhancing wellness, there will be a continued call for the medical device industry to consider the environmental, health and safety implications of not only patients and health care workers, but also the health of communities and the natural environment.

Over recent decades, several key technical trends have shaped the current state of product safety, performance, and clinical efficacy in today's health care setting. Currently, the medical device industry is facing an emergent trend which will add new considerations in the assessment of market acceptability of medical devices and services. Based on historical practices and projected future demands for safe medical devices and services, the medical device industry must assess and reconfigure its guidelines to include additional safety and efficacy precautions that protect the patient, health care workers, and the communities they serve, incorporating an environmental health perspective. This document will offer suggestions to consider; that which constitutes a sustainable option might vary in any given situation.

Explosive population growth combined with massive industrialization and development over the past centuries have created environmental and health challenges to which all industries, but particularly those dedicated to improving human health, must respond. The natural resources humans depend on for life are being consumed at a growing rate; science has begun to link exposure to certain chemicals to negative health impacts in humans, and the scientific community has shown that global climate change will have serious and nearly immediate impacts for human health and the environment.¹ The World Health Organization recognizes these risks² and estimates the direct damage costs to health at between \$2-4 billion USD per year by 2030.³

Sustainable development has been described as the "Triple Bottom Line" where three resources intersect: 1) Society; 2) Economy; and 3) Environment. Where these priorities overlap is where businesses will thrive by providing products that serve customers, reduce costs and offer enhanced environmental health and safety (EHS) benefits. There are numerous global drivers for sustainability within the medical supplier industry: countries require it, customers demand it, investors reward it, and employees desire it.

Compliance with 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 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Restriction of Hazardous Substances (RoHS) might lead to supply disruptions until the nonconformance is corrected.

Various research demonstrates the interest in Sustainability in both the health care industry and in employee recruitment. Data from a global research study conducted with health care professionals in 2014⁴ found that more than half of respondents report their hospitals currently incorporate sustainability into purchasing decisions, and more expect that to be the case within two years. The research also identified a strong belief among respondents that sustainability drives direct business and social benefits. About eight in ten respondents said sustainable products help protect hospital staff and seven in ten said they make good financial sense. Additionally, more than half said 'green initiatives' are an important factor for patients when choosing a hospital and that they help improve health outcomes.

Studies concerning human resources show that sustainability attracts and retains employees, which helps to maintain critical talent within the organization. A 2012 Net Impact survey⁵ found that respondents would be willing to take a pay cut to work for an organization committed to corporate social responsibility, to have a job that makes a social or environmental impact, and to work for an organization whose values are like their own. Over half of the students and those in the current workforce said that "making the world a better place" was very important or essential in the ideal job.

Consideration to the sustainable use of environmental and social resources will impact the financial sustainability of a company and using resources efficiently—using less energy, water, and producing less waste help lower costs. Investment companies are now assessing sustainability measures in the areas of Environment, Society and Governance for determining investment recommendations. Managing risks associated with these environmental and social resources 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. Assets in sustainability-focused managed funds now exceed

\$5 trillion and companies are being recognized for their focus on sustainability strategies and programs through inclusion on indexes such as the Dow Jones Sustainability Index and FSTE4Good Index. Increased transparency around sustainability performance, particularly when using globally recognized programs such as the Global Reporting Initiative (GRI) and Carbon Disclosure Project (CDP) can provide both economic and reputational value to an organization.

This Technical Information Report was written as a US document with a US focus. The committee considered proposing an International Standards Organization (ISO) activity on this topic but came to the decision to start with a US document and gauge its reception. Many of the participants in the health care value chain are global companies that have to meet requirements in each country they do business. We encourage users outside of the US to consider this document as a framework that must be modified to meet the needs in various parts of the world.

This Technical Information Report does not attempt to define whether a specific design is sustainable or not, rather it seeks to create a framework for the discussion by suggesting that sustainable design is achieved when economically viable, clinically acceptable designs are created that significantly reduce important environmental and societal concerns relative to other available options. While sustainability is an important consideration, when evaluating sustainable design options for application to single patient, single-use disposable medical devices or durable equipment for multiple patient uses, one must always require that the medical device delivers its intended clinical use, within specified performance parameters during the expected life of the medical device. Changes in product composition, components, manufacturing process, or storage conditions made to comply with sustainability objectives should be fully evaluated within risk analysis procedures to assess the impact of required or desired sustainability objectives. Examples include:

- The transition from lead-based solder alloys to alternative alloys has required reliability and life cycle testing on compliant assemblies and manufacturing practices. Virtually all electronics assemblies were designed to withstand manufacturing with the use of tin/lead solder and the temperatures they required. Lead-free options require higher temperatures and the resultant assemblies have required additional shock and vibration testing to assure long term reliability. Study has shown that lead-free failure times, failure mechanisms and failure locations differ from the lead based alloys.⁶ Careful attention to technical assessment and process change adoption should enable successful adoption of lead free solder.
- There has been a desire to move away from natural rubber latex to synthetic alternatives and to reduce, or eliminate, accelerators (potential chemical sensitizer) from these synthetic alternatives. Studies have shown that glove durability is a function of polymer type but have also shown that durability within a given polymer type is variable by composition. Accelerator free synthetic gloves (nitrile) might be more prone to failure due to use and mechanical stresses.⁷
- Latitude has been sought in allowed lower humidity limits for operating rooms (OR) and OR storage. New building standards allow operation to a lower humidity limit of 20 percent.⁸ In some instances, materials used to provide the sterile items used in this environment (sterile medical packaging and the biological indicators required to indicate sterility) haven't been validated to maintain stability and integrity for prolonged periods at the lower humidity. In other instances, critical care ventilators used in the OR have been validated to perform at a lower limit of 30 percent relative humidity.⁹

Manufacturers should consider sustainability in their manufacturing and distribution decisions, while ensuring consistency with the Federal Trade Commission's Guides for the Use of Environmental Marketing Claims "Green Guides." Users/purchasers should consider sustainability in their purchasing and use decisions.

Sustainability of medical devices—Elements of a responsible product life cycle

1 Scope

This Technical Information Report (TIR) is intended to highlight sustainability considerations during the product design, supply chain, manufacturing, acquisition, use, and end of life of medical devices, taking into account the life cycle impacts of the product. These sustainability considerations include economic, environmental, and societal issues. This TIR provides suppliers, manufacturers, distributors, and users/purchasers with a framework including qualitative metrics to utilize as they strive to increase transparency, reduce and mitigate potential negative impacts, and encourage positive impacts for the health and safety of the community.

2 Normative references

ANSI/AAMI EQ89, *Guidance for the use of medical equipment maintenance strategies and procedures*

ANSI/AAMI ST91, *Flexible and semi-rigid endoscope processing in health care*

ANSI/AAMI/ISO 11607-1, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ANSI/AAMI/ISO TIR11139, *Sterilization of health care products - Vocabulary*

AAMI TIR12, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*

ASTM D6400, *Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities*

ASTM D6868, *Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities*

3 Informative references

AAMI White Paper, *Elements of a responsible product life cycle*

IEC 60601-1-9, *Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design*

IEC 62474, *Material declaration for products of and for the electrotechnical industry*

ISO 10993, *Biological evaluation of medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14001, *Environmental management systems -- Requirements with guidance for use*

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

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

ISO 50001, *Energy management systems -- Requirements with guidance for use*

ISO Guide 82, *Guidelines for addressing sustainability in standards*

CA Prop 65, *Safe Drinking Water and Toxic Enforcement Act of 1986*