An Environmental Guide for the Medical Device Industry in Massachusetts

Prepared By:

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Executive Office of Environmental Affairs
Office of Technical Assistance and Technology

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OTA also formed a Medical Device Sector Advisory Board representing industry associations, manufacturers, product designers and other key stakeholders to assist in the preparation of this Guide. OTA gratefully acknowledges the significant contributions of the Board through their review and insightful comments:

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- Lucy Servidio, Senior Environmental Scientist, Capaccio Environmental Engineering, Inc.

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Figures and Tables

Purpose of this Guide

Consider this Guide a roadmap. It presents a map to the environmental issues inherent in the design and manufacture of medical devices, including the landmarks, opportunities and roadblocks facing professionals in the sector. It shows different routes to consider in search of a product destination. And it lists points of interest and highlights along the way. Hopefully, it raises awareness of key issues and provides ACCESS to the information that you need when you need it.

This Guide is designed for professionals in the medical device sector who wish to:

- Learn more about Design for the Environment (DfE) and Pollution Prevention (P2) concepts, resources and tools
- Identify relevant environmental requirements and issues, and access the corresponding environmental regulations
- Obtain compliance assistance and guidance, and
- Access case studies or examples

The audience for this guide includes product designers and manufacturing engineers, facilities personnel, and environmental, health and safety (EHS) professionals. We hope the guide is also useful to research, purchasing, quality, compliance and business development professionals in this sector.

According to the Harris Full Profile Reports, there are more than 250 companies in Massachusetts listed as manufacturers of surgical and medical equipment, electromedical and electrotherapeutic apparatuses, and surgical appliances and supplies

Companies targeted by this guide are small and medium-sized manufacturers of surgical and medical equipment, electromedical and electrotherapeutic apparatuses and surgical appliances and supplies – as well as **their product design firms, their suppliers and original equipment manufacturers (OEMS).** Larger companies may find the guide useful (1) as an internal resource to engage engineers and design professionals; (2) as an awareness raising tool to distribute to suppliers and OEMS to better manage supplier risk and align strategic product priorities; or (3) to share with customers as part of corporate efforts to demonstrate commitment to enhanced environmental performance.

Background

This Guide is the outgrowth of nearly three years of work by the Massachusetts Executive Office of Environmental Affairs (EOEA) and the Office of Technical Assistance (OTA) with the medical device sector, including workshops and on-site technical and compliance assistance visits.

The Office of Technical Assistance is a non-regulatory service provider to all Massachusetts toxics users and is a part of EOEA. The mission of OTA is to promote toxics use reduction, improved environmental performance, health

Visit OTA's website
http://www.mass.gov/envir/ota/

and safety, economic competitiveness in the private sector, and effective service delivery in the public sector.

In **2004**, OTA hosted a **focus group** of medical device company representatives and product design professionals for the purpose of: better understanding the environmental challenges and opportunities associated with the design, manufacture and sale of medical device products; recognizing opportunities for regulatory improvements and streamlining; and identifying the types of services that could be provided by OTA. The background document *FINAL REPORT: Setting Your Agenda for Environmental Performance: A Focus Group with Massachusetts Medical Device Manufacturers* is available on the OTA website. Representatives from more than a dozen medical device manufacturers in Massachusetts participated in the focus group and provided insights that are incorporated into this report.

In June **2005**, OTA organized and hosted a **workshop** on *The Business Case for Design for the Environment (DfE) for Medical Device Manufacturers.* The workshop report and presentations are available on the OTA website. Thirty individuals from twenty four (24) companies, business organizations, academia and federal and state government participated in the workshop. The agenda included a 45-minute Executive Session, followed by a longer technical session. The Executive Session was led by Dr. Patrick Eagan, a professor at the University of Wisconsin with more than ten years of DfE experience consulting to medical device manufacturers and healthcare organizations. Dr. Eagan also provided a detailed DfE presentation for the technical session, in addition to presentations from Bayer Healthcare, Johnson and Johnson and Hospitals for a Healthy Environment.

"The key is to understand where global environmental regulations and public concerns are heading, and make strategic business and product decisions to seize emerging opportunities and avoid risks that new products will soon be obsolete or further regulated" - Dr. Patrick Eagan OTA Workshop June 2005

For additional information on OTA's activities with the medical device sector, contact the OTA sector leader, Dr. John Raschko.

Advisory Board

An Advisory Board, comprised of eleven experts representing industry associations, manufacturers, product designers and other key stakeholders, assisted greatly in the development of this Guide. Interviews with these industry leaders helped us:

- Understand the unique features of this sector (e.g., growth patterns, organizational structure, business models);
- Identify the key environmental compliance requirements applicable to the industry; and
- Gain insights into the challenges and opportunities to address environmental issues in the design of tomorrow's medical devices.

Their review of the draft guide ensured that it contained relevant information presented in a tone and format that would be of greatest value to the various professionals involved in making medical device design, manufacturing and use decisions that may ultimately impact the environment.

The Office of Technical Assistance and Technology

The Office of Technical Assistance and Technology (OTA) provides a range of non-regulatory assistance services to all Massachusetts toxics users, at no cost and on a confidential basis. Since its creation in 1990, OTA has successfully assisted Massachusetts businesses in various industry sectors with reducing the use of over 200 million pounds of toxic chemicals, while saving more than $22 million. OTA provides services to help businesses cut costs, improve chemical use efficiency, and reduce environmental impact in Massachusetts. Specific services and programs include:

- Non-regulatory on-site technical and compliance assistance
- Pre-permit assistance program ("Right from the Start")
- Informative and educational conferences, workshops, and seminars
- Advisory and guidance publications – fact sheets, case studies, and technical reports
- Identification of new pollution prevention technology and research needs of industry
- Software applications that can help facilities monitor operations, improve efficiency, reduce waste and comply with particular reporting requirements

A more detailed description of OTA's compliance assistance activities is found in Appendix A.

OTA has made more than 3,600 site visits to over 1,200 Massachusetts facilities.

Nearly 40% of the 500 TURA filers OTA has worked with are no longer required to file TURA reports.

In total, these Massachusetts companies achieved reductions of more than 210 million pounds of toxic chemicals and over $22 million in savings.

How to Use This Guide

The five major sections of this Guide follow a roadmap, as illustrated on the following page, which is designed to help medical device manufacturers answer such questions as:

- What type of environmental attributes do I wish to consider for my products?
- How can I minimize environmental impacts associated with my product design and manufacturing?
- What are others doing?
- Is our manufacturing facility complying with applicable environmental regulations?
- What are the consequences of not complying with environmental regulations?
- Where can I find compliance assistance and guidance?

You don't need to read the Guide cover to cover to find the answers to these questions. Product designers, engineers, environmental professionals and regulatory compliance personnel are likely to ask different questions, and need different information. Therefore, we have organized the sections of the Guide to assist this broad range of readers to readily access the information they need.

It is intended that the Guide be used as an electronic document to allow the user to take advantage of the internal and external links that have been built into it. The ***internal links*** will help you navigate the Guide by allowing you to quickly access relevant information. In addition, we have included ***graphical icons*** in the upper right corner of each page to identify the various sections of the document

Contact OTA if you find that any of the external links are no longer functional

There are examples of companies utilizing DfE and medical products with environmental attributes scattered throughout this Guide, as well as a comprehensive ***Case Studies*** section at the end of the document.

Roadmap to the Information in this Guide

The chapter entitled ***What's Driving Design for the Environment?*** provides information about integrating environmental issues into the process of designing and manufacturing new or modified products and the drivers, such as European Standards, for Design for the Environment (DfE) and pollution prevention (P2). The icon below in the upper right corner identifies this section on drivers.	The chapter ***DfE Approaches*** outlines major avenues and approaches to achieving your environmental goals, whether it is as simple as basic compliance with applicable standards or regulations, or a broader commitment to enhanced efficiency, toxics use reduction, or using recycled materials. The icon below identifies this key section of the Guide.	***Concept Development - The DfE Toolbox*** discusses and provides information, insights and examples of tools a manufacturer should consider when putting together a program to assess environmental issues in the design of your next product or reengineering of existing products.	***Roadblocks to DfE*** discusses the many challenges faced by designers, and environmental, health and safety professionals, in trying to incorporate environmental criteria and influence the product design decision-making process.	***Environmental Compliance and the Manufacture of Medical Devices***, the second Section of this Guide, provides an overview of potentially applicable regulatory requirements facing medical device manufacturers in Massachusetts. We have also included practical information, such as compliance calendars and common violations, to assist you to comply with applicable standards. There are also links to information describing the possible consequences of environmental violations.
Look for this symbol 	Look for this symbol 	Look for this symbol 	Look for this symbol 	Look for this symbol **Compliance**

What's Driving Design for the Environment?

Design for the Environment (DfE) – designing a product to minimize environmental impacts over the product or service's entire life cycle - is not a new concept. Since the early nineties, retail and consumer companies have incorporated DfE or ecodesign concepts into their product development processes and marketing campaigns. These approaches were ultimately woven into environmental management systems, green marketing campaigns and, more recently, sustainability initiatives and reporting.

It's no surprise that the five medical product companies in the Fortune 500 have a strong commitment to environmental management:
Medtronic
Baxter International
Boston Scientific
Becton, Dickinson and Co.
Stryker

These efforts in the nineties to "green" companies demonstrated that: (1) well-managed, successful companies are likely to have strong environmental management systems and programs; and (2) more consumers, when faced with competing products of equal value or cost, are likely to purchase a "greener" or "healthier" product. However, only a small percentage of customers will sacrifice cost or quality for products with stronger environmental attributes.

The drivers for environmental performance improvement for the medical device sector also appear to be about new or emerging business models, which suggests that successful and profitable companies selling in a global, highly regulated marketplace must:

- Get ahead of environmental compliance issues
- Integrate environmental requirements, values and commitments into core business activities
- Listen to customers' concerns and desires, including avoidance of certain toxic constituents and questions concerning product life cycles and costs

The business case for promoting Design for the Environment in the medical device sector is being driven by the following forces:

1. European and international environmental standards are driving environmental issues in product development
2. Lean manufacturing and quality management systems in the medical device sector are driving down production costs and can effectively complement and support environmental performance improvements
3. Hospitals and hospital purchasing organizations are beginning to apply economic leverage to encourage "healthier" products within the healthcare sector

European and International Standards

Europe – not the United States – is setting environmental standards for international commerce and forcing changes in how medical devices are made. Medical device manufacturers, and their suppliers, in Massachusetts need to conform to European rules if they wish to have a share of that market. With 25 countries and nearly 500 million people, Europe surpasses even the market in the United States for healthcare equipment. Add stringent environmental standards in Japan and strong indications that China will follow Europe's lead and, well, you get the picture.

European Union

The Massachusetts Toxics Use Reduction Institute has hosted workshops on compliance with emerging European standards. Check out http://www.turi.org

Building on prior environmental standards applicable to packaging and batteries, emerging regulations in Europe are directly affecting the materials used in the design and manufacture of products. No matter where you are in the supply chain, these European directives will affect your business as you must "remake what you make" and demonstrate and certify compliance to these standards for each component in a product.

Product designer and architect William McDonough describes strategies for "remaking what you make" at his website http://www.mbdc.com/

The European Union regulations – as well as emerging standards in Japan, Korea and China – should be tracked carefully. Despite this driving influence, there's a sense of "ho hum" by some in the medical device sector because the far-reaching Directive on Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS) currently excludes medical device products and the Directive on Waste Electrical and Electronic Equipment (WEEE) is only now being implemented after years of delays. It's time to pay attention to these influential drivers and compliance concerns.

Directive on Waste Electrical and Electronic Equipment (WEEE)

This Directive requires producers of electronic products that are sold in the EU to be responsible for reducing electronic waste. The Directive applies to medical devices, with the exception of implanted and infected products. Medical device companies must therefore consider dismantling and recovery in the product design process, and setting up or participating in systems for the recovery and recycling, or reuse, of waste electrical and electronic equipment. Medical device products offered for sale in Europe must be registered for WEEE in all EU countries. Each Member State manages its own WEEE registration system, so the medical device "producer" who is subject to WEEE must submit registrations in each country.

Medical devices are currently covered by the WEEE Standard which requires, among other things, identification of the material (e.g., polypropylene) and labeling of electronics components with the icon below

Information about WEEE can be found at http://www.buyusa.gov/europeanunion/weee.html

While enforcement continues to be a bit of a mystery, non-compliance poses potential financial risk to manufacturers as well as supply chain companies, and a potential public relations nightmare.

Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS)

This Directive bars the use of hazardous substances, including lead, mercury, cadmium and other toxic materials in electrical and electronic equipment sold in the European Union. While RoHS is closely linked to WEEE, most medical devices are currently excluded from its requirements. Such equipment as radiotherapy equipment, cardiology, dialysis, pulmonary ventilators, laboratory equipment, in-vitro diagnosis equipment and other devices for detection may be covered by the standard. It is anticipated that the directive will eventually cover all medical devices. Medical device companies are finding out, however, that RoHS is already impacting their products because many electronic equipment suppliers or OEMS are being forced to use "lead free" solder and make other component substitutions. The directive required that lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs) in electrical and electronic equipment had to be replaced by other substances by July 1, 2006. As it is not always possible to completely abandon the use of these substances, there are allowances provided for negligible tolerance levels (e.g., 0.1% for cadmium) or for limited exemptions.

Medical devices are currently excluded from the RoHS Standard. That may soon change in Europe and elsewhere in the world. For example, China is likely to implement its version of RoHS – without the medical device exemption – in 2008.

This may change, however. The European Commission is currently evaluating whether to include medical devices under the scope of RoHS. A study is being carried out for the Commission by an independent consultant, Dr. Paul Goodman of ERA Technology, into the feasibility and desirability of such an inclusion. The report is due to be finalized in 2006, and will be followed by a public consultation on its results. The Commission will then subject its ideas on revision to an impact assessment, and then its proposals will be published and will go through the normal EU legislative procedure. This process will take several years, so it is unlikely that any inclusion would enter into force before 2009 at the very earliest (and more likely 2010).

Many medical device companies are striving to be RoHS compliant in advance of future deadlines. While that is to be encouraged, there are decision-making challenges when faced with non-mandated product substitutions (e.g., lead-free) that pose product quality challenges.

It should also be noted that there is legislation in China (often referred to as "China RoHS) that has similar restrictions and will cover medical devices. This legislation is slated to take effect in 2008. Japan, on the other hand, does not have similar legislation, but its stringent recycling laws have spurred electrical and electronic manufacturers in that part of the world to move to a lead-free process.

More information on RoHS can be found at the WEEE website cited above.

Registration, Evaluation and Authorization of Chemicals (REACH)

The REACH framework, while still a proposal, would require EU producers and importers to submit toxicity and use information for about 30,000 chemicals, and it introduces an authorization procedure for the use of up to 1,400 very hazardous chemicals. It places the responsibility and cost for collecting and analyzing information about these chemicals on industry. This legislation is likely to have significant impacts on chemical suppliers to the medical device sector. While some experts suggest that REACH adoption is imminent, many multinational chemical suppliers are strongly opposed to its passage.

The REACH Standard has not yet been finalized

Information about REACH can be found at http://www.buyusa.gov/europeanunion/reach.html

Energy Using Products (EuP)

The European Union Framework For Setting Eco-design Requirements for Energy Using Products (EuP) will likely be law in 2007 or 2008. Moving rapidly though the legislative process and wider in scope than any related existing EU legislation, this Directive has the potential to create requirements for manufacturers of products selected by its "implementing measures" to demonstrate that their designs are energy efficient and that an environmental life cycle assessment was performed.

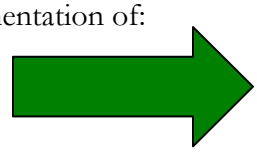
Information on the EuP Directive can be found at http://ec.europa.eu/enterprise/eco_design/index_en.htm

In addition to the EuP legislation, the European Commission adopted a directive in 2003 that requires the collection of, and new recycling targets for, all types of batteries in the European market. The directive also mandates the recovery of the heavy metals in batteries to keep the potentially toxic waste from being landfilled or incinerated. Under the new directive, battery producers are responsible for all costs related to collection, treatment, and recycling. Earlier regulations applied only to batteries containing specific quantities of cadmium, lead, or mercury, and proved to be inefficient deterrents for keeping batteries out of final disposal facilities.

Management System Approaches

Another driver for environmental performance improvements in the medical device manufacturing sector is the natural linkages between Design for the Environment (DfE), pollution prevention (P2) and implementation of:

- Quality Management Systems;
- Lean Manufacturing; and
- Six Sigma



Pollution Prevention
DfE

Pollution Prevention (P2) is often defined as source reduction and other practices that reduce or eliminate the creation of pollutants through: increased efficiency in the use of raw materials, energy, water, or other resources, or protection of natural resources by conservation. P2 is a natural outcome from any of these leading management initiatives.

Implementation of these three complementary approaches to continuous improvement, quality control and efficiency has been successfully used by medical device facilities, and their suppliers, to promote and achieve environmental performance goals in the manufacture and distribution of products

Quality Management Systems

These systems describe the process, and a set of interrelated policies and procedures, for assuring product quality. These systems follow the maxim: "Say What You Do, and Do What You Say". In the FDA environment, quality audits are required to help improve product quality and safety — and to ensure conformance with product specifications. The Quality System Regulation (21 CFR Part 820) requires medical device companies to monitor their quality systems through audits. Under the Current Good Manufacturing Practice (CGMP) principles outlined in the QSR, quality audits are considered a necessary part of a self-correcting quality system. For ISO-certified manufacturers, ISO 9000 requires evaluation of the quality system and examination of audit results by management, while ISO 14000 calls for internal environmental management audits. ISO 13485 requires regular internal audits as a way of monitoring and measuring quality.

Lean Manufacturing

Lean manufacturing is a management philosophy focusing on reduction of the seven wastes (Over-production, Waiting time, Transportation, Processing, Inventory, Motion, and Scrap) in manufactured products or any type of business. The key thrust of "lean manufacturing" is to improve the speed of processes by reducing or eliminating waste. Opportunities such as energy efficiency, conservation of raw materials, recycling of solid wastes, reduction in air emissions, water conservation and hazardous waste minimization can be addressed through lean manufacturing.

The key lean manufacturing principles are:

- Perfect first-time quality - quest for zero defects, revealing & solving problems at the source
- Waste minimization – eliminating all activities that do not add value, maximize use of scarce resources (capital, people and land)
- Continuous improvement – reducing costs, improving quality, increasing productivity and information sharing
- Pull processing – products are pulled from the consumer end, not pushed from the production end
- Flexibility – producing different mixes or greater diversity of products quickly, without sacrificing efficiency at lower volumes of production
- Building and maintaining a long term relationship with suppliers through collaborative risk sharing, cost sharing and information sharing arrangements

DJO Inc., a manufacturer of rehabilitation and regeneration products for the non-operative orthopedic and spine markets, was awarded the Shingo Prize for Excellence in Manufacturing for its use of Lean techniques. Click here for more information.

The Massachusetts Manufacturing Extension Partnership (MEP) can assist companies in implementing Lean Manufacturing techniques.

Six Sigma

Six Sigma is a methodology to manage process variations that cause defects, defined as unacceptable deviations from the mean or target, and to systematically work towards managing variation to eliminate those defects. The objective of Six Sigma is to deliver world-class performance, reliability, and value to the end customer. It was pioneered by Bill Smith at Motorola in 1986 and was originally defined as a metric for measuring defects and improving quality. Six Sigma has now grown beyond defect control. Six Sigma is a registered service mark and trademark of Motorola, Inc. Motorola has reported over $17 billion in savings from Six Sigma to date.

This project-oriented, quantitative approach has been successfully used to improve production efficiency and minimize wastes associated with manufacturing activities.

Healthcare Marketplace

Interest in environmentally preferable purchasing has grown significantly over the past few years, according to Sarah O'Brien, co-director for Hospitals for a Healthy Environment (H2E). H2E (http://www.h2e-online.org/) is a not-for profit organization whose mission is to help healthcare facilities enhance work place safety, reduce waste and waste disposal costs, and become better environmental stewards and neighbors.

H2E has been working for several years with seven major Group Purchasing Organizations (GPOs), which together have a combined purchasing of over $60 billion and an interest – and some cases, a goal – of purchasing products with certain environmental attributes to meet their customers' needs. For example, Kaiser Permanente instituted in 2004 a comprehensive chemicals policy to limit the use or exposure of toxic chemicals in the healthcare setting.

GPOs Partnering with H2E

GPO	Website
Amerinet	http://www.amerinet-gpo.com
APS (Associated Purchasing Services)	http://www.apskc.org
Broadlane	http://www.broadlane.com
Consorta	http://www.consorta.com
MedAssets HCA	http://www.medassets.com
Novation	http://www.novationco.com
Premier, Inc.	http://www.premierinc.com

In Massachusetts alone, there are more than 60 "H2E Partners" – hospitals and healthcare organizations – that have taken the H2E pledge to make changes in their facilities that protect their communities' health and the environment.

While GPOs and the institutions they represent continue to prioritize quality and cost in the purchase of products, these organizations are now increasingly interested in product compliance with applicable international, federal, or state standards and may be interested in "green" products (e.g., PVC-free) which can successfully compete on price and quality with existing products. At the CleanMed conference in spring 2006 in Seattle, WA, executives from five of

these GPO organizations presented at or attended the conference along with 500 other healthcare professionals and leaders. At the conference, Baxter and Hospira both introduced new PVC-free IV products and it was announced that more than 110 health care organizations had expressed commitments to reduce PVC or DEHP. For example, Catholic Healthcare West announced its intention to award a $70 million contract for a PVC-free product line.

There are a number of not-for-profit advocacy groups, such as Healthcare Without Harm, that are focused on affecting change in the purchasing practices of the healthcare sector. While initial P2 efforts focused on removing mercury from hospitals, the toxics avoidance emphasis has expanded considerably over the last several years. The following list describes the current slate of environmental purchasing preferences, according to the environmental advocacy community:

"Green purchasing" is also gaining momentum from governmental purchasing and academic purchasing consortiums

- Products that comply with EU chemical prohibitions and restrictions
- Mercury free products
- PVC-free products
- Latex-free products
- DEHP-free products
- Brominated flame retardant – free products
- Formaldehyde-free products
- Non-toxic solvents and dyes
- Products free of Persistent or Bioaccumulative Toxics (PBTs)
- Needle devices complying with federal legislation
- Reusable products

The word, and the pressure to make modifications to purchasing, is spreading. In addition to the U.S. conference attended by 500 people, CleanMed Europe 2006 in Stockholm, Sweden attracted an even larger crowd. The stated purpose of the conference was to "raise awareness of the environmental problems in the healthcare sector and to speak knowledgably on how to solve these problems. CleanMed Europe also aims to be the meeting point for all healthcare professionals with an interest in improving the environmental performance of the healthcare sector."

CleanMed Europe

It is recommended that medical device companies listen to and participate in medical device associations such as MassMEDIC, EUCOMED or ADVAMED

It is important that medical device companies and their product designers track these advocacy organizations or have a forum to listen to the concerns, and opportunities, expressed by the purchasing organizations and professionals who will be making key business decisions.

Building the Business Case

Successful medical device companies are pursuing various strategies that build the business case for integrating environmental issues into the corporate culture. These models may include, but are not limited to:

- Pursuing a strong corporate sustainability program that strives to integrate financial, social and environmental factors into the business plan and build a "sustainable" company.
  - *For example, **Smith & Nephew** publishes an annual sustainability report http://www.smith-nephew.com/sustainability2003/index.html*
- Listening to and understanding environmental stakeholders, and developing products that meet these "needs" in a diverse and ever-changing global marketplace.
  - ***Baxter** and **Braun** are two companies that have built successful partnerships with environmental stakeholders.*
- Focusing on productivity and efficiency in manufacturing.
- Reinventing and remaking the fundamental materials and assumptions behind products.
  - ***Metabolix** makes proven biodegradable plastics from renewable materials http://www.metabolix.com/*
- Developing a formal DfE program that is integrated into the culture of the business.
  - *While medical device companies such as DePuy and Medtronic have formal DfE programs, check out **Dell**, **Cisco** and **Motorola** for further examples of formal, comprehensive DfE programs in other sectors. Information on Dell's program can be found here.*

DfE Approaches

Design for the Environment (DfE) is BEING DONE in the medical device sector. Environmental improvements, such as the use of less toxic inks and reduction of waste, are often successfully integrated into packaging design. Devices are being made smaller, using fewer resources, and wireless, which can lead to reduced environmental impacts. Lead-free solder and an infrastructure to return and recycle electronics is slowly gaining ground as a result of the European Environmental Directives. And there is a growing wave of influences, such as Green Chemistry, lean manufacturing, and rising fuel costs that are likely to significantly impact how we think about products, the materials we use, and how they are manufactured.

"Dell has established a Design for the Environment (DfE) Program to integrate environmental attributes into each aspect of the product life cycle, from supplier management during component manufacturing to end-of-life solutions."

There are a number of reasons why DfE has been adopted in the medical device sector: there's a business case for it; compliance with environmental requirements; access to international markets; reduced production costs; and customer concerns. So, what's different about a product development process that uses DfE? Companies that follow these principles will, in theory:

- Design product life cycles, rather than just products
- Select materials using different criteria than employed in the past
- Consider the entire manufacturing process, including byproducts, emissions, energy, and water usage
- Be concerned about the fate of the product after its useful, intended life

The Dell Environmental Product Design Program includes programs to:

- Manage the product life cycle

- Implement EMS at manufacturing facilities

- Improve product energy efficiency

- Verify compliance

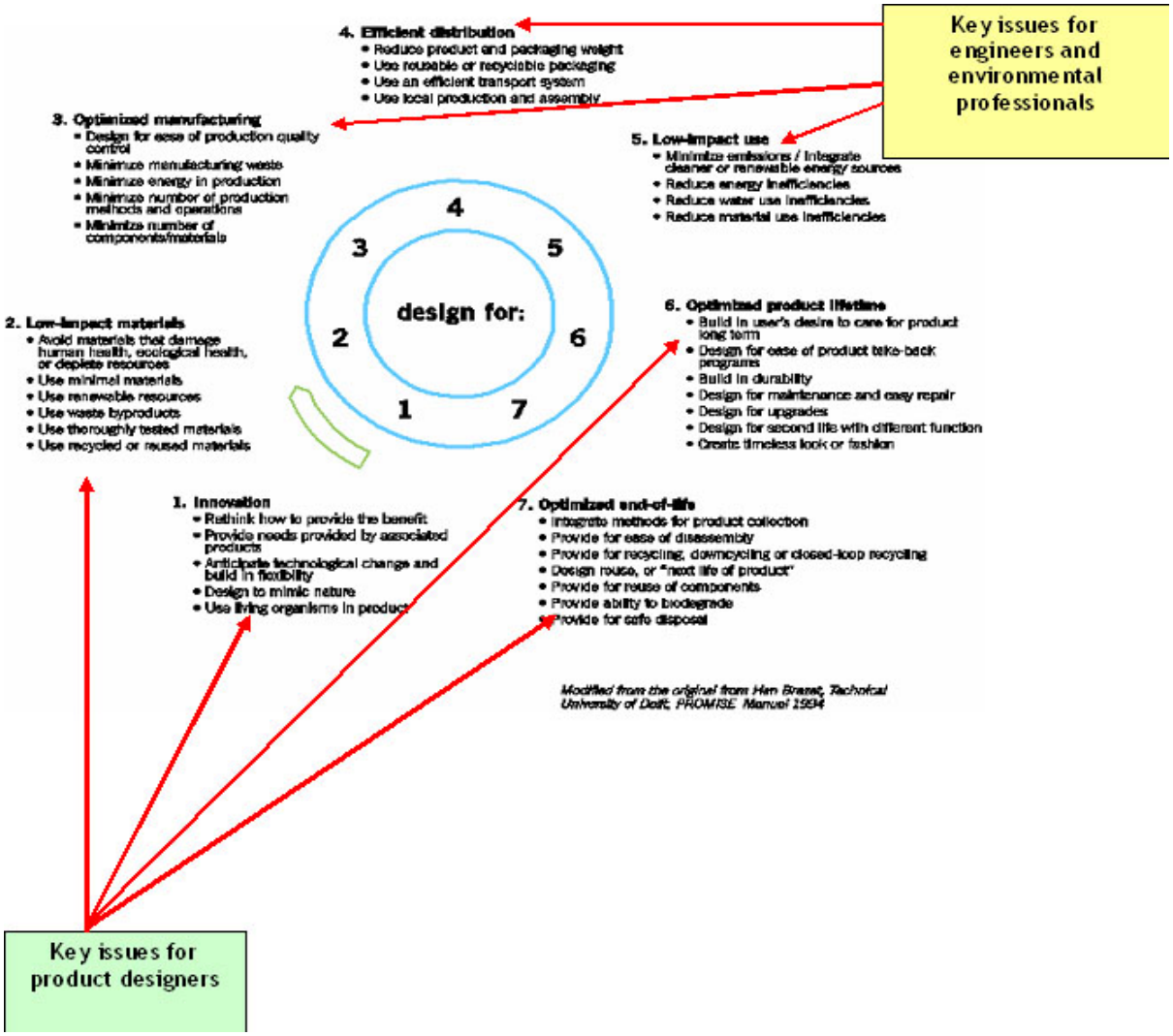
This section identifies some methods and approaches that can be used to integrate DfE concepts into the traditional product design process, with emphasis on medical device applications. The illustration on the next page, from the IDSA Ecodesign section website (modified from Hans Brezet, Technical University of Delft), identifies some of the common methods available to minimize environmental impacts over the life of a product.

Provided in the discussion of each DfE approach are a number of links to more detailed information, including the Case Studies in the Guide.

General Resources/Links for Product Designers

- IDSA Medical Device section - http://new.idsa.org/webmodules/articles/anmviewer.asp?a=374&z=66
- Global Network for Sustainable Design - http://www.O2.org
- American Society of Mechanical Engineers - http://www.asme.org
- U.S. Dept of Energy Efficiency and Renewable Energy - http://www.eere.energy.gov
- Environmental Protection Encouragement Agency - http://www.epea.com
- Recycler's World - http://www.recycle.net

- U.S. Green Building Council - http://www.usgbc.org
- McDonough & Braungart Design Chemistry - http://www.mbdc.com/index.htm
- Center for Sustainable Design - http://www.cfsd.org.uk
- Environmentally Sustainable Product Design Resource – http://www.espdesign.org



Reduce Toxic Materials

Every product should be designed and manufactured to comply with existing international standards and to minimize toxics that may impact patient health or be released to the environment as a result of improper management. While finding suitable substitutes can be a formidable challenge, the Office of Technical Assistance (OTA) and the Toxics Use Reduction Institute (TURI) are leaders in helping facilities and conducting research in this area.

New materials, such as bio-based polymers, are being researched and developed by corporate giants like GE and Cargill, as well as emerging technology companies like Metabolix.

OTA and TURI, along with MassDEP, implement the Toxics Use Reduction Act (TURA). The TURA program is a $3+ million effort dedicated to assisting Massachusetts industry to prevent pollution at the source. In particular, the TURA requirements to develop toxics use reduction plans have played an important role in the reduction of toxic chemicals from Massachusetts manufacturing facilities.

Information on the TURA program can be found at OTA's website, along with a document describing P2 and toxics use reduction (TUR).

Electronic medical devices can contain the following toxic substances:

- Cadmium (batteries, pigments)
- Lead (Circuit board solder, batteries, CRTs)
- Mercury (switches, relays)
- Beryllium (circuit substrates, spring steel alloys)
- Phthalates (additives to polymers)
- Brominated flame retardants (on circuit boards and in plastics)
- Hexavalent Chrome

In addition to the toxics found in electronic products, efforts should be made to reduce the use of toxic coatings, paints, pigments, binders, adhesives and finishes that are applied to the product and that may be generated as byproducts from production. Product designers and production engineers should be familiar with the EU prohibitions on the use of certain materials (e.g., Lead, Chrome VI); customer demands from hospitals and their purchasing programs for toxic chemical substitutions (e.g., products free of latex, PVC, and DEHP); and policies or goals directing the medical device manufacturing company or client away from certain toxics.

Work with suppliers: advances in components -- adhesives, coatings and tubing -- extend beyond the medical device sector.

The Toxics Use Reduction Institute at the University of Massachusetts Lowell recently issued the ***Five Chemicals Alternatives Assessment Study*** to the Massachusetts Legislature that identified less toxic alternatives for five toxic chemicals. One of the chemicals is di(2-ethylhexyl) phthalate (DEHP), a commonly used chemical in the medical device manufacturing industry. A number of alternative compounds were identified, as described in the Executive Summary of the Study (a link to the study is to the right):

Information about the potential uses of the five chemicals in other applications, their toxicity, and environmental impacts are discussed in the report. Click here to access the report.

"The Institute assessed five alternative plasticizers for use in medical devices:

- Trioctyl trimellitate (TOTM) is a clear, oily liquid that is a high production volume plasticizer in the U.S. In the medical device industry, TOTM is currently used primarily in blood and bag infusion sets

- Di (2-ethylhexyl) adipate (DEHA) has properties that make it a useful plasticizer for materials used to store medical solutions that must be kept cold
- Butyryl trihexyl citrate (BTHC) is a plasticizer specifically designed for use in medical articles, especially blood storage bags
- Di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH) is the hydrogenated product of the corresponding di C9 phthalate ester (DINP)
- Di isononyl phthalate (DINP) is currently used as a plasticizer in medical tubing devices."

Resources/Links

- Plastics
  1. PVC-free and DEHP-free medical devices - http://www.noharm.org/us/pvcDehp/PVCfree
  2. Society of Plastics Engineers - http://www.4spe.org/
- Solvents/Cleaners
  1. OTA Report Barriers to Eliminating Chlorinated Solvent Use In Cleaning Operations At Massachusetts Manufacturers - http://www.mass.gov/envir/ota/publications/pdf/barriers_to_tce_reductions_final_2006.pdf
  2. Solvent Alternatives Guide - http://clean.rti.org
  3. TURI Cleaner Solutions Database (solvent substitution) – TURI - CleanerSolutions Database
  4. Alternative cleaners (medical devices, electronics, metal finishing) - http://www.ensolv.com/I_metalfinishing.htm
  5. Metal Surface Cleaning/Degreasing Database – http://www.cleantool.org
- Metal Finishing
  1. National Metal Finishing Resource Center - http://www.nmfrc.org/
  2. Metal finishing techniques - http://www.electrohio.com/Index.htm
  3. Machining medical device parts - http://www.reedlink.com/SingleArticle~ContentId~56261~pub~MD.html
  4. Environmental Products & Services for the Finishing Industry - http://www.finishing.com/Environmental/index.html
- Paints/Coatings
  1. Paints and Coatings Resource Center - http://www.paintcenter.org/
  2. OTA Powder Coating Technical Fact Sheet - http://www.mass.gov/envir/ota/pubs/powder_coating_fact_sheet.pdf
  3. OTA Powder Coating FAQ Fact Sheet - http://www.mass.gov/envir/ota/support/powder_coating_faq_final.pdf
- Electronics
  1. OTA Document: Best Management Practices for the Manufacture of Electronics with Lead Solder - http://www.mass.gov/envir/ota/publications/pdf/bmp_for_lead_final_web.pdf
  2. TURI Supply Chain programs (Wire and Cable, Lead-free Electronics) - http://www.turi.org/content/content/view/full/2311/
  3. EPA DfE projects (e.g., lead-free solder, printed circuit boards) - http://www.epa.gov/dfe/pubs/projects/index.htm
  4. Circuits Assembly (electronics P2 information) - http://www.circuitsassembly.com/cms/

- Other P2 Resources
  1. Collection of P2 options for various industrial operations - http://www.zerowastenetwork.org/P2Options/index.cfm
  2. OTA P2 Case Studies - http://www.mass.gov/envir/ota/publications/case_studies1.htm
  3. OTA P2 links - http://www.mass.gov/envir/ota/links/links.htm#_Pollution_Prevention_Links
  4. Pollution Prevention Resource Exchange (P2Rx) - http://www.p2rx.org/
  5. Great Lakes Regional Pollution Prevention Roundtable - http://www.glrppr.org/hubs/
  6. Pacific Northwest Pollution Prevention Resource Center - http://www.pprc.org/
  7. Northeast Waste Management Officials' Association (NEWMOA) P2 program - http://www.newmoa.org/prevention/
  8. National Pollution Prevention Roundtable (NPPR) - http://www.p2.org/about/
- Case Study: AVIVA PVC-Free Intravenous Solution Containers
- Case Study: VISIV Flexible Intravenous Container from Hospira

Practice Green Chemistry

Green Chemistry is the design of products and processes that reduce or eliminate the use and generation of hazardous substances, and seeks to reduce and prevent pollution at its source. Green Chemistry can serve as a framework for guiding product designers and researchers, as a tool used by biomedical engineers in designing more efficient production processes, or as a policy framework for governmental policy. For example, California recently established a state framework for a move toward Green Chemistry, in which policies are designed to motivate industry investment in the design and use of chemicals that are less toxic, do not accumulate in the body, and break down more readily in the environment. Green chemical manufacturing processes also use safer materials and less energy, and they produce less hazardous waste.

Winners of EPA's Green Chemistry awards include Metabolix for its bio-based plastic, BASF for a UV-coated, low VOC refinish primer, and Atmospheric Glow Technologies for an innovative method for cold sterilization.

OTA has been a leader in promoting Green Chemistry, supporting workshops as early as 2002.

OTA was awarded a grant of $150,000 by the John Adams Innovation Institute in September 2006 to develop high speed direct digital printing of textile substrates with radiation curable dyes and pigments.

OTA has collaborated with researchers at Carnegie Mellon University to demonstrate the use of the TAML® activator/catalyst for color removal from wastewater.

In general, Massachusetts has been a leader in Green Chemistry, and a resource for practitioners, for many years. One of the co-founders of the Green Chemistry approach is Dr. John Warner of the University of Massachusetts-Lowell. The Toxics Use Reduction Institute has also utilized a Green Chemistry paradigm in conducting its Five Chemicals Study, as previously discussed in this guide. In addition, the toxics use reduction law and planning model is consistent with a Green Chemistry approach.

The Office of Technical Assistance (OTA) is a strong advocate for incorporating Green Chemistry practices into manufacturing operations. Since the office's inception, OTA has recommended less toxic alternatives to manufacturers that use toxic chemicals in their operations. In addition, OTA hosted two symposia on Green Chemistry in manufacturing and continues to include Green Chemistry in OTA sponsored events, has developed a number of case studies that cite successful Green Chemistry techniques, has worked on projects with industry and academia to develop and implement new Green Chemistry-related technologies, and continues to make Green Chemistry recommendations through their on-site technical assistance program. One example of an OTA technology development project involving collaboration

with industry and academic researchers is the effort to assist Churchill Coatings, a wood prestainer, in developing zero-VOC coatings and coating technologies (such as radiation curing) as alternatives to solvent based coatings. This project is also an example of how environmental enforcement and policy can be coupled with technology development to improve environmental quality and enhance competitive manufacturing in Massachusetts.

The 12 Principles of Green Chemistry are described below:

Principle	Description
1. Prevent waste	Design chemical syntheses to prevent waste, leaving no waste to treat or clean up.
2. Design safer chemicals and products	Design chemical products to be fully effective, yet have little or no toxicity.
3. Design less hazardous chemical syntheses	Design syntheses to use and generate substances with little or no toxicity to humans and the environment.
4. Use Renewable feedstock	Use raw materials and feedstock that are renewable rather than depleting. Renewable feedstocks are often made from agricultural products or are the wastes of other processes; depleting feedstocks are made from fossil fuels (petroleum, natural gas coal) or are mined.
5. Use catalysts, not stoichiometric reagents	Minimize waste by using catalytic reactions. Catalysts are used in small amounts and can carry out a single reaction many times. They are preferable to stoichiometric reagents, which are used in excess and work only once.
6. Avoid chemical derivatives	Avoid using blocking or protecting groups or any temporary modifications if possible. Derivatives use additional reagents and generate waste.
7. Maximize atom economy	Design syntheses so that the final product contains the maximum proportion of the starting materials. There should be few, if any, wasted atoms.
8. Use safer solvents and reaction conditions.	Avoid using solvents, separation agents, or other auxiliary chemicals.
9. Increase energy efficiency	Run chemical reactions at ambient temperature and pressure, whenever possible.
10. Design chemicals and products to degrade after use.	Design chemical products to break down to innocuous substances after use so that they do not accumulate in the environment.
11. Analyze in real time to prevent pollution.	Include in-process, real-time monitoring and control during syntheses to minimize or eliminate the formation of byproducts
12. Minimize the potential for accidents.	Design chemicals and their forms (solid, liquid or gas) to minimize the potential for chemical accidents including explosions, fires, and releases to the environment.

Resources/Links

- OTA Green Chemistry case studies –
  - Crane & Co. - http://www.mass.gov/envir/ota/publications/cases/crane_case_study.pdf
  - ESP Lock Products Inc. - http://www.mass.gov/envir/ota/publications/cases/esp_lock_case_study.pdf
  - Tubed Products - http://www.mass.gov/envir/ota/publications/cases/tubed_products.pdf
- EPA Green Chemistry Website - http://www.epa.gov/greenchemistry
- EPA's Green Chemistry Expert System - http://www.epa.gov/oppt/greenchemistry/pubs/tools.html
- The 12 principles of Green Chemistry - http://en.wikipedia.org/wiki/Green_chemistry#
- Green Chemistry Institute - http://www.chemistry.org/portal/a/c/s/1/acsdisplay.html?DOC=greenchemistryinstitute\index.html
- MIT's Green Chemical Alternatives Purchasing Wizard (Solvents) - Environment at MIT - Research and Academic Programs
- Article: Practical Approaches to Green Solvents - http://www.ucsf.edu/chem111/currentevents/greensolvents2002.pdf
- Newspaper Article - Green Chemistry Takes Root (USA Today)
- Center for Green Chemistry at University of Massachusetts Lowell - http://www.greenchemistry.uml.edu
- Green Chemistry Experiments for Education, University of Oregon - http://greenchem.uoregon.edu/gems.html
- NSF Science and Technology Center for Environmentally Responsible Solvents and Processes (UNC at Chapel Hill) - http://www.nsfstc.unc.edu/
- TURI Five Chemical Study - http://www.turi.org/content/content/view/full/2739/

Expand Options for Recyclability/Disassembly

Designing medical products for recyclability and disassembly is admittedly difficult because of the unique materials and fastening approaches used to ensure that medical devices can withstand the demanding challenges posed by a healthcare setting. Designers should think, however, about such aspects of the product as:

- Using commonly recyclable materials, as appropriate
- Simplifying hinges (e.g., graphically indicate break away areas)
- Stamping the resin type on all plastic parts
- Minimizing additives and foaming agents that may drive up the cost of recycling

What if disassembly is not what the client wants? The key to good design is allowing the client to make informed "conscious" choices - Is disassembly or recycling an option? Can it be done? Does it make sense?

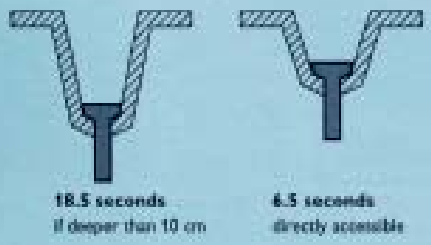
Figure 1 on the next page, from the IDSA Okala Guide, illustrates some of the issues associated with design for disassembly.

Figure 1

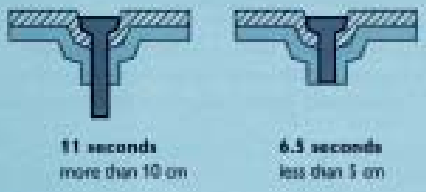
Connections for disassembly

Screws

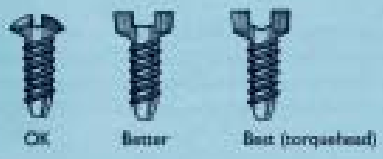
Make screws visible and accessible



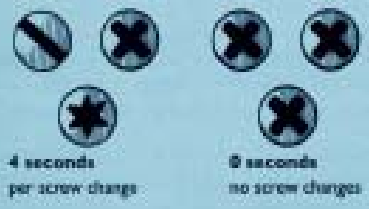
Make screws no longer than needed



Use the best screwheads



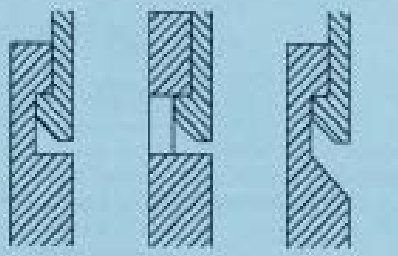
Use one type of screwhead per product



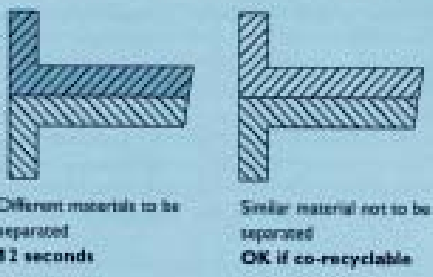
Use ferromagnetic metals

Other Connections

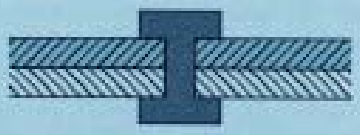
Click-fits
Make directly accessible and visible
(do not use more than 3 per part)



Glued joints
Use only recycling-compatible glues



Rivets: 13 seconds



Wire Twisty: 2 seconds

Pressfits: 3 seconds

Stake welding: 3 seconds

Metal belt with screw: 15.5 seconds

Philips Corporate Design's Guidelines for Ecological Design, **Green Pages**, 1996, Eindhoven, The Netherlands

The description below, from the Hewlett-Packard Sustainability Report, describes their approach for ***design for recyclability***.

The appropriate disposal of used computers and other electronic equipment is an increasing global concern. Hewlett-Packard has worked for many years to design products that are easier to recycle. We operate several recycling facilities, which allows us to determine the most effective design features to facilitate product recycling.

This experience has resulted in the development of our Design for Recycling (DfR) standards to improve the ability of products to be recycled. These design features include:

- **Using modular design to allow components to be removed, upgraded or replaced**
- **Eliminating glues and adhesives by using, for example, snap-in features**
- **Marking plastic parts weighing more than 25g according to ISO 11469 international standards, to speed up materials identification during recycling**
- **Reducing the number and types of materials used**
- **Using single plastic polymers**
- **Using molded-in colors and finishes instead of paint, coatings or plating**

HP's DfR standards integrate clear design guidelines and checklists into every product's design process to assess and improve a product's recyclability. This allows HP to develop products that are easier to recycle.

Resources/Links

- Article on the Okala Program - http://www.idsa.org/webmodules/articles/articlefiles/Steve_Belletire_et_al.pdf
- H-P Global Citizenship Report (2005) - http://www.hp.com/hpinfo/globalcitizenship/gcreport/products/designrecycle.html
- Case Study: Davol Simpulse Lavage

Use Recycled Materials

Medical device companies and product designers are hesitant to use recycled materials if there are real or perceived issues associated with patient contact. Despite that concern, there is ample opportunity to use such materials as recycled steel, aluminum, glass and paperboard.

In addition to "post-consumer" recycled material, opportunities can be explored with the plastic supplier to use pre-consumer recycled material -- scrap material from the manufacturing process -- which is reworked back into production.

In cases where patient contact is not an issue, plastic components can be made from recycled plastic. The potential use of recycled materials should be discussed with suppliers to determine (1) if the material to be purchased already includes a substantial recycled content; and (2) the cost of requesting, or increasing the percentage of, recycled stock.

Manufacturers should always explore the use of pre- and post-consumer recycled materials in packaging materials. Often, the use of recycled materials can be prescribed in the component specifications sent to the supplier.

Resources/Links

- Commonwealth of Massachusetts Environmentally Preferable Products (EPP) procurement program - http://www.mass.gov/epp/enviro.htm
- Plastic Recycling Resources - http://www.plasticsresource.com/s_plasticsresource/doc.asp?TRACKID=&CID=40&DID=420
- Recycler's World - http://www.recycle.net

Reduce Waste

According to Hospitals for a Healthy Environment (H2E), hospitals in the U.S. produce 6,600 tons of waste per day (e.g., paper, cardboard, batteries). Much of the increase is the result of an increased use of disposable items. Efforts by product designers to address this problem come in two forms.

First, designers should strive to minimize waste (i.e., cost of disposal) by decreasing the volume of material, reducing the weight of material, and minimizing the disposal of entire items as "biohazard" when only a small fraction of the device is potentially contaminated.

Second, product manufacturers and designers should consider extending the useful life of the product, including a consideration of any "reusable" parts of disposable devices.

As described in the section "Roadblocks to DfE", efforts to reduce waste at the point of use must battle against the trend to make single use medical devices. Production engineers and designers continue, however, to find opportunities to reduce waste despite this trend.

Resources/Links

- TURA Data Extracts- http://www.mass.gov/dep/toxics/priorities/tursucce.htm
- OTA Conference on P2 for the Healthcare Industry - http://www.mass.gov/envir/ota/pubs/medp2wrkshp.htm#Introduction
- Waste Reduction Resource Center (e.g., electronics, metal finishing and cleaning, packaging) - http://wrrc.p2pays.org/industry/indsector.htm
- Waste Reduction Resource Center (Hospital and Medical sector) - http://wrrc.p2pays.org/industry/hospital.htm
- Hospitals for a Healthy Environment - http://www.h2e-online.org
- Case Study: Symphony® Breastpump by Medela
- Case Study: DYONICS™ 25 Fluid Management System

Provide the Service in an Innovative Way

Many businesses are rethinking not only what they make, but what they do. Are they a product manufacturer? Or, are they a service provider? The business model of a company can significantly affect the development of products.

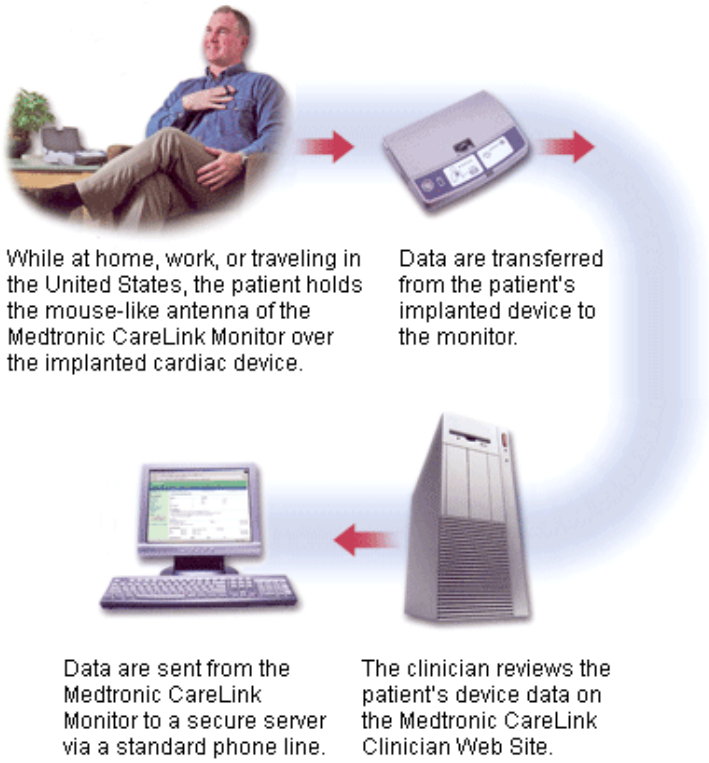
Develop different use scenarios during the research phase of design so the design team can rethink "how the product provides benefit."

Reflect on the primary service that your product delivers, and conceptualize possible ways that this service can be delivered with lower ecological impact. For instance, can a patient use the device at home without coming to a healthcare setting? Can the analytical powers of a single diagnostic piece of equipment be broadened so that it replaces a trip to a specialist or the manufacture of multiple pieces of equipment?

The new medical reality is that monitoring devices and analytical equipment are increasingly wireless, which minimizes various environmental impacts and promotes "service" over "product."

Two simple examples may suffice. Neither was driven by "environmental" reasons. First, conventional x-ray machines are being replaced by digital x-ray equipment. The digital x-ray equipment is inherently safer for patients and decreases the use of film and chemicals associated with traditional x-rays. This method also avoids radiation safety paperwork compliance and reduces long-term equipment disposal costs.

Second, many diagnostic tests/products are now regarded as services in which the testing, information data transmission, analysis and reporting are done in a matter of minutes, as illustrated in the Medtronic example that follows.



Resources/Links

- Two leading "visionaries" in this area:
  - Paul Hawken - http://www.paulhawken.com/
  - William McDonough - http://www.mbdc.com/
- Case Study: Digital X-Ray

Improve Energy Efficiency

Energy efficiency is important to any product that plugs into a wall socket, uses batteries, or burns fossil fuel. A number of opportunities exist for medical device companies to address energy efficiency:

Increase The Energy Efficiency Of Your Manufacturing Facility

This can be achieved through energy efficiency improvements to equipment such as lighting and HVAC systems, chillers, motors, fans, pumps, and process lines, and will pay dividends and add environmental gains to your products. DOE's Office of Energy Efficiency and Renewable Energy (EERE) leads the Federal government's research, development, and deployment efforts in energy efficiency. The Industrial Technologies Program (ITP), a component of EERE, partners with U.S. industry to improve industrial energy efficiency and environmental performance. BestPractices, a program of ITP, works with industry to identify plant-wide opportunities for energy savings and process efficiency. Technical assistance activities such as plant assessments, system optimization software tools, training, information and technology dissemination, and showcase demonstrations are all available to stimulate near-term adoption of energy management best practices and technologies. A variety of industrial systems are addressed through BestPractices.

Don't overlook human energy! Automation or technology is not always the answer. Human energy can replace machine energy. For example, human preparation of samples may be the cost-effective, energy efficient answer.

Links to most of the investor owned and municipal electric and gas suppliers in Massachusetts can be found at the Division of Energy Resource's website.

In addition, Massachusetts manufacturing facilities may wish to take advantage of utility Demand Side Management (DSM) programs which provide technical support and funding for energy efficiency audits and equipment rebates as a method that benefits utilities and customers by better managing energy demand. Specific DSM strategies may include enhanced energy efficiency, load management, or fuel substitution. If your energy supplier is a municipal utility, there may only be limited incentive programs available.

ISO New England, the operator of the electric grid in New England, offers Demand Response programs that compensate large electricity users for reducing consumption when market prices are high or demand is high and system reliability is at risk. Users may choose from among different options designed to fit their needs. Also check with your electricity provider for information on these programs, as well as specific load management programs offered by the provider.

Resources/Links

- DOE websites –
  - Office of Energy Efficiency and Renewable Energy - http://www.eere.energy.gov/

- EERE Industrial Technologies Program - http://www1.eere.energy.gov/industry/
- BestPractices Program - http://www1.eere.energy.gov/industry/bestpractices/
- DOE energy efficiency case studies - http://www1.eere.energy.gov/industry/bestpractices/case_studies_industry.html

- OTA Energy Conservation website - http://www.mass.gov/envir/ota/resources/energy_conserv.htm
- Some utility energy efficiency incentive programs -
  - Electric – National Grid (NGRID), Western Mass Electric (WMECO)
  - Gas and electric - NSTAR
  - Natural Gas - KeySpan, Bay State Gas
- ISO New England Demand Response programs - http://www.iso-ne.com/genrtion_resrcs/dr/index.html
- The Center for Energy Efficiency and Renewable Energy (CEERE) at UMass Amherst - http://www.ceere.org/iac/index.html (provides technical and economic solutions to environmental problems resulting from energy production, industrial, manufacturing, and commercial activities, and land use practices. CEERE provides eligible small- and medium-sized manufacturers with no-cost energy assessments. For more information, contact Dr. Beka Kosanovic at (413) 545-0684).
- Massachusetts Energy Efficiency Partnership (MAEEP) – http://www.maeep.org (CEERE at UMass Amherst, with US DOE and Massachusetts DOER support, has developed a strategic partnership with Massachusetts electric utilities (NGRID, NSTAR, and WMECO) to improve the energy efficiency and productivity of industry. Call your account representative and ask about ways to work with MAEEP and your utility. Or contact MAEEP by email or call Dr. Chad Nelson (Director) at 413-545-2853 to find out more.
- Northeast Combined Heat and Power Initiative and The Northeast CHP Application Center - http://www.northeastchp.org/

Design Products To Be More Energy Efficient

One driver for designing more energy efficient products is the increase in wireless and portable devices. Weight requirements and use times demand very efficient circuitry, which minimizes battery use and, therefore, the size and weight of the product.

Companies may choose to demonstrate the energy efficiency of their products through designation as an "Energy Star" product under the program jointly run by EPA and DOE. For example, the company BlueAir achieved Energy Star rating for its air purifiers (click on the figure to the right), which are listed as medical devices under the Food and Drug Administration. The company believes that this "branding" will support sales to healthcare organizations and home consumers.

Consider also that the EU's Energy-using-Products (EuP) Directive, while still evolving, is likely to require manufacturers of energy using products to perform an assessment of the environmental aspects of a product throughout its life cycle. Companies will have to evaluate environmentally relevant product characteristics, including measurements of both energy inputs and outputs. The

product should then be designed, or redesigned, according to this environmental assessment and decisions recorded and justified.

Resources/Links

- Energy Star program - http://energystar.gov/index.cfm?c=business.bus_index
- Energy Star tools and resources (on-line training, financial calculators) - http://energystar.gov/index.cfm?c=tools_resources.bus_energy_management_tools_resources
- DOE Energy-Efficient Products website - http://www.eere.energy.gov/femp/procurement/
- Case Study: Symphony Breastpump by Medela

Commit To Reductions Of Carbon Emissions Through Innovative Programs

For example, DePuy New Bedford has purchased "green tags" to offset carbon emissions and meet its company's Greenhouse Gas Emission reduction targets at a time of production growth. Purchase of renewable energy credits, green tags or installation of renewable technologies may be implemented at the facility level. There's no reason that a product can't be "carbon neutral" based on such a strategy.

Many leading corporations (such as BP, GE, and Toyota) have implemented plans to reduce carbon emissions.

The organization CERES recently issued a report entitled 2006 Corporate Governance and Climate Change: Making the Connection that uses a "Climate Governance Checklist" to evaluate how major industrial corporations are addressing climate change in five broad areas: board oversight, management performance, public disclosure, greenhouse gas emissions accounting, and strategic planning. The report took nine months to complete and uses data from securities filings, company reports, company websites, third-party questionnaires and direct company communications.

Using a 100-point scoring system, the report ranked the largest companies in the oil/gas, electric power, auto, chemical, industrial equipment, mining/metals, coal, food products, forest products, and air transportation sectors with operations in the United States. The scoring system gave most credit to companies with a sustained commitment to controlling greenhouse gas emissions, disclosing data and strategies, supporting regulatory actions, and taking practical, near-term steps to find lasting solutions to climate change. Top performers included BP, DuPont, Unilever, General Electric and Toyota.

Resources/Links

- CERES Report - http://www.ceres.org/pub/publication.php?pid=84
- Pew Center on Global Change - http://www.pewclimate.org/
- Web searches: use terms such as "climate change", "policy", "commitment" and a company name to find further examples. For example, "Intel" and "climate change policy" identifies several sites that articulate the company's commitments and activities in this area.

Conserve Resources

Medical products should be designed to reduce material, manufacturing, and energy costs. The use of minimal quantities of materials (including water), the use of similar materials for ease of recycling, and the use of a minimal number of components will likely save money and reduce environmental impacts. These benefits can be quantified financially and environmentally.

Ask basic questions: "Is an overmold or elastomer part necessary, or just cool?" A "grab area" or "touch point" may actually be better and more durable as a hard part.

Some of these concepts are also described in the **Green Chemistry** and **Energy Efficiency** sections of this chapter.

Resources/Links

- OTA Water Conservation website (company success stories, BMPs, other links) - http://www.mass.gov/envir/ota/resources/water_conserv.htm
- Toxics Use Reduction Institute - www.turi.org
- Case Study: Medtronic Oxygenator
- Case Study: Davol Simpulse Lavage
- Case Study: DYONICS™ 25 Fluid Management System
- Web search results for: "lean manufacturing", "Six sigma" or "pollution prevention"

Extend or Rethink Product Life

Companies should estimate the period of time that the product is typically used before it is thrown away and evaluate environmental issues over the entire life cycle. Designers should ask themselves such questions as:

Designers can – and should – rethink product function, and question fundamental assumptions about product use and life -
What is durable?
Why only one use?
Why does a device only perform one function?

- Can the product be redesigned to be more durable, upgradeable or repairable?
- Is there market information indicating whether or not a longer lasting, and possibly more expensive, product is desired.

Product life can be extended through (1) leasing arrangements, (2) production of more durable equipment, and (3) reuse.

For example, Hitachi Medical Corporation offers a number of laparoscopic and ultrasound probes that are classified as reusable medical devices.

As noted before, single use devices are now more prevalent because of concerns about cross-contamination; cost factors; and liability concerns. Despite the trend toward the use of disposables, products are reused in certain circumstances – when it makes financial sense, the risk of human error is minimal, and the potential for contamination is irrelevant.

The reuse of "single use" devices is a contentious topic within the sector.

In addition to products that are designed for extended product life, some single use devices are "reprocessed" at FDA approved facilities for reuse. For example, disposable medical products (such as gowns, oximetry probes, basins, batteries, and ventilator circuits) may be reprocessed by a third party firm and reused.

Resources/Links

- EPA Product Stewardship website - http://www.epa.gov/epr/
- Product Stewardship Institute website - http://www.productstewardship.us
- IBM Product Stewardship policy - http://www.ibm.com/ibm/responsibility/world/environmental/products.shtml

Evaluate Transportation Patterns and Supplier Issues

Think about the product life cycle, not just the product. Opportunities to save money, reduce fuel usage and limit emissions associated with efficient manufacture and distribution of products should not be overlooked.

Improvements in transportation logistics and supply chain management may save money and generate reductions in carbon emissions, petroleum usage and air pollution that can dwarf other efforts to reduce environmental impacts.

Quantifying the environmental benefits of these supply chain distribution and logistics decisions only serves to help the DfE cause and the connection between strong environmental programs and smart business.

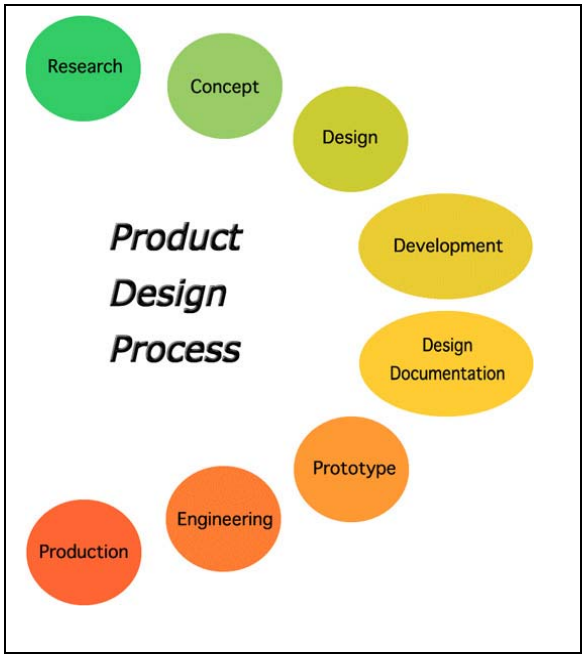
Resources/Links

- H-P Global Citizenship Report (reduction of environmental impacts through logistics) - http://www.hp.com/hpinfo/globalcitizenship/gcreport/supplychain/transport.html
- Sony Corporate Social Responsibility website (reduction of environmental impact in logistics) - http://www.sony.net/SonyInfo/Environment/environment/logistics/index.html
- Case Study: NC-Stat System from Neurometrix

Consider some user assembly if it allows for decreased manufacturing energy use or smaller shipping size.

The DfE Toolbox

The basic process of designing a medical device is well understood. It follows the process illustrated below. At each stage of this process, however, tools must be available to guide and support decision-making that considers the environmental impacts associated with the product or service. Based on our research, the tools described in this section should help you on your path.



On the pages that follow, information about the components of a tool box are presented in the left-hand column, and information about the potential "user" of the tool is presented on the right, along with other key messages.

For a substantial list of general links regarding DfE and product design, check out the Industrial Designers Society of America (IDSA) ecodesign section website at:
http://www.idsa.org/whatsnew/sections/ecosection/selectedlinks.html.

"Design usually starts with "There is No way,' and then we say 'Okay, How can we make this work?'"
Jochen Zeitz, CEO, Puma

In 2004, Johnson and Johnson evaluated 99% of their products and processes for their environmental impacts.

According to a 2004 IDSA Product Designers "Survey on Electronic Product Ecodesign Influence", the most common source for material environmental impact information was the use of the world wide web. The least common source of information was the client.

Tool	Audience/User
Company Policy Companies with an expressed, formal policy that values compliance with environmental regulations and includes a commitment to minimize environmental impacts can be a useful tool to prod, encourage, and cajole mid-level managers and engineers to align decision-making with corporate policy. For example, Johnson and Johnson says the following in its annual sustainability report: Our credo commits us to "maintain in good order the property we are privileged to use, protecting the environment and natural resources." This is a fundamental aspect of the corporate culture at Johnson & Johnson. As a large, multinational organization, our environmental footprint is complex and far-reaching. We have standard procedures in place requiring that each of our worldwide facilities characterize and understand the environmental impacts of their operations, plan for emergencies and seek opportunities for continuous improvement. On a corporate level, we establish goals that drive us toward reducing our overall consumption of resources, increasing the efficiency of our operations, and minimizing the adverse effects of waste. ***Resources/Links*** • Search Engine Terms: "environmental" or "sustainability" and "policy" for specified companies. For example, this term and "Medtronic" comes up with the Medtronic Environmental, Health and Safety Policy - http://www.medtronic.com/corporate_governance/env_health_safety.html • Smith and Nephew Health, Safety and Environmental Policy Statement - http://www.smith-nephew.com/who/principles-hse.html	***All employees, but most notably mid-level managers and engineers who may lose sight of corporate policy as design costs and production timelines influence decision-making***
DfE Team A team. A DfE Team. The team needs to understand the company's policy and the toolbox available to them, as well as receive appropriate training to ensure that the framework for decision-making is well understood, tools are effectively used and environmental goals achieved. ***Resources/Links*** • Some good introductory materials on DfE can be found at - http://www.epa.gov/opptintr/dfe/pubs/ • Conduct a search on "team building" or "multi-disciplinary" or "cross-function" teams for some basic information on teams.	***All relevant employees involved in the product design process*** ***For example, the DfE team at Hewlett-Packard helped balance a "cool" look with the desire to increase the recyclability of the plastic printer components. The team agreed on a metal case instead of painted plastic and the printer – model DJ6540 – won awards for industrial as well as environmental design.***

Tool	Audience/User
Inventory of Applicable Requirements It is important that a company maintain an inventory of applicable international, federal or state environmental requirements, including existing and pending chemical prohibitions and bans, packaging and labeling requirements, and recycling standards. In addition to the database of existing requirements, an inventory of pending or potential requirements should be readily available, such as RoHS and REACH, so that companies can evaluate the risk of a product becoming obsolete or prohibited in the future. This database can be built in-house by the regulatory staff, provided by a consultant, or accessed though a service or software solution that can identify applicable legal requirements and assist with materials compliance declarations. This inventory can then be integrated with internal standards and future goals to create corporate standards. For example, a company may identify: Tier 1 Substances - to be prohibited immediately, such as cadmium, mercury, and hexavalent chrome. Tier 2 Substances – to be phased out in predetermined phases, such as PVC for specific applications or lead solder. Tier 3 Substances – to be phased out in the future, such as DEHP. ***Resources/Links*** • RoHS compliance management system software, e.g., http://www.hclbpo.com/ • IDSA Ecodesign Section - http://www.idsa.org/whatsnew/sections/ecosection/ • Search Engine Terms: "EU environmental standards", "WEEE" and "RoHS" compliance for multiple sites.	***Product designers Regulatory and legal officers Design engineers*** ***In a 2004 IDSA/EPA Ecodesign Information Needs Survey, the #1 information need of working product designers was international environmental regulations.*** ***Manufacturing companies should share information early and often with their design team about applicable environmental requirements, chemical prohibitions, and packaging requirements to allow their timely input.*** ***A new product's potential global reach should be identified early so that applicable requirements can be identified.***

Tool	Audience/User
Framework for Decision-Making DePuy, a Johnson and Johnson company with facilities in Massachusetts, uses a structured framework for integrating DfE into the product design process. In the 2004 Johnson and Johnson Sustainability Report, they describe that process as follows: **Review of New Products and Processes** Design for the Environment (DfE) is our process for identifying and minimizing the environmental impacts of new and modified products and processes. The computer based DfE tool uses a quantitative scoring system that rates processes based on environmental factors, such as energy use, water use, hazardous material requirements, process efficiency and yield, and nonproduct output (NPO) generation. This scoring mechanism allows designers to quickly compare the overall environmental friendliness of a variety of options. Johnson and Johnson's goal is to design products that are more environmentally friendly by integrating DfE into every aspect of developing a new product or process. R & D organizations across the corporation are responsible for implementing DfE, with environmental professionals serving as coaches for the evaluation process. From the time a new product is just a concept, through development, manufacturing, sales, marketing and ultimately disposal or recovery of the product, DfE helps identify negative environmental impacts and options for mitigating these impacts. The DfE tool enables users to identify restricted or banned substances and evaluate country-specific regulations surrounding chemical use, packaging and disposal. Designers can also assess the impacts of new products or processes on energy use, raw material consumption and waste generation. By making sound decisions early in a product's development, we can improve performance while preventing the need for costly retrofits to address environmental problems that may be identified later. This provides significant business advantage. **Designing Products to Minimize Environmental Impacts -** Ortho-Clinical Diagnostics, Inc. (OCD) in Raritan, New Jersey (a J&J company), is working toward a complete phase-out of the preservative thimerosal, which contains mercury. OCD decreased its annual usage of mercury by 80 percent from 2000 to 2004 by applying DfE principles to product development and periodic review of processes. By reducing mercury and its presence in products, OCD is avoiding the ultimate disposal of mercury, which tends to bioaccumulate, and may be harmful to human health and the environment if not managed properly. All remaining OCD products containing thimerosol are scheduled for replacement with mercury-free products by 2008. ***Resources/Links*** • J & J Sustainability Reports - http://www.jnj.com/community/environment/publications/index.htm	***All employees involved in new product design, process re-engineering and environmental, health and safety functions.*** ***More than a checklist, a process and framework for decision-making create business value from what others may see as environmental constraints.*** ***"This provides significant business advantage."*** ***A product designer suggested the need for a tool to share with customers that allows for an evaluation of environment-directed "trade-offs." This tool would allow a client to better understand his/her decisions and the impact of her/his choices. It also helps the design team deal directly with the trade-offs – e.g., Pb free –that may pose significant challenges.***

- J & J Environmental Programs - http://www.jnj.com/community/environment/index.htm
- Ortho-Clinical Diagnostics Governors Award for Solvent Reduction - http://www.dec.state.ny.us/website/ppu/success/ortho.html
- "Environmentally Conscious Design Support Tool in Early Stage of Product Development", Japan Environmental Management Association for Industry (JEMAI) - www.jemai.or.jp/english/dfe/pdf/20_4.pdf

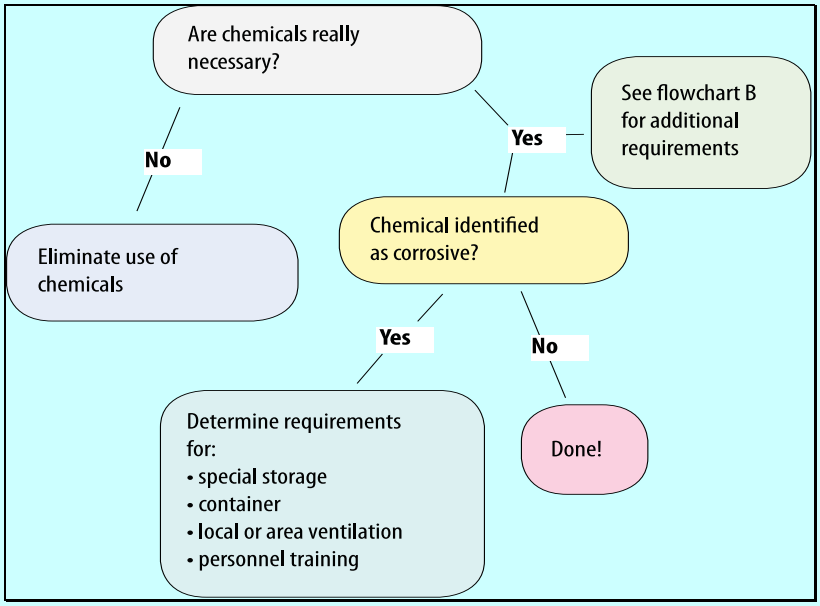
DfE Checklist/Procedure

All members of new product or production change team

EH&S staff

Some companies have developed Design for the Environment (DfE) checklists to ensure that critical environmental and manufacturability issues are addressed – and addressed early in the process. For example, Medtronic has available two tools that can be used by the design team to evaluate environmental concerns. One of the tools, called the Environmental Product Design Evaluation Plan, consists of yes/no questions, a series of easy-to-read flow charts and related documents. A second tool, the Materials Productivity Process Overview, is used to identify opportunities to improve the efficiency of materials use and the production operations. Both tools are used after the product conceptualization phase, but during the product design stage when the feasibility is studied and a prototype is developed. An example of these tools is illustrated below, and is also included as Appendix B:

An example of a DfE checklist is presented in Appendix B consisting of two parts that are used together. Appendix B-1 is an EHS Evaluation Checklist and Appendix B-2 is an EHS Product Design Evaluation Plan.



It is important to use a DfE checklist tool early in the process - EH&S managers often lament that they are asked to use these tools so late in the process that they have limited ability to influence decision-making.

Based on our interviews, we know that Johnson and Johnson, Bayer Healthcare, Tyco Healthcare and other large medical device companies have developed comprehensive DfE checklists that cover product design, materials, production and end-of-life issues.

Resources/Links • Pollution Prevention Resource Center (PPRC) DfE checklist - http://www.pprc.org/pubs/epr/dfe.pdf • Medtronic DfE case study - http://www.moea.state.mn.us/publications/dfe-medtronic.pdf • EPA DfE tools - http://www.epa.gov/dfe/tools/index.htm • Example of a P2 checklist - http://www.epa.state.il.us/p2/fact-sheets/p2-checklist.pdf	
Materials Databases Access to a comprehensive database of materials (e.g., chemicals, plastics) which contain information about environmental impacts, toxics, and energy usage is extremely valuable in selecting materials for components. For example, the architect and product designer William McDonough and chemist Michael Braungart have, over the years, developed a proprietary database that they use to conduct a thorough scientific assessment of the material chemistry of components. The McDonough-Braungart Design Chemistry approach enables them to recommend materials based on the material chemistry, in concert with a defined framework for decision-making. Some of the commercially available Life Cycle Assessment tools, as well as company-specific tools, have databases for commonly used chemicals and materials. The IDSA is developing a database of commonly used materials and impact factors for the majority of the materials listed in Table 1. ***Resources/Links*** • IDSA Ecodesign Section - http://www.idsa.org/whatsnew/sections/ecosection/ • McDonough and Braungart - http://www.mbdc.com/ • Center for Sustainable Design in the UK - http://www.cfsd.org.uk/index.html • University of Waterloo - http://crmd.uwaterloo.ca/eng.html • US Life Cycle Inventory Database - http://www.nrel.gov/lci/	***Research and development*** ***Product designers*** ***Process engineers*** ***For example, a core standard for Cisco Systems is "materials innovation" in which opportunities are identified to incorporate materials and components that will reduce environmental impacts of Cisco products and packaging.***

Table 1
IDSA Materials Table

Material or process	OTHER MATERIALS	METALS
POLYMERS	Brown cardboard	Cast iron, grey
ABS	Cardboard secondary	Steel
HDPE polyethylene	White paper	Steel secondary
HDPE polyethylene secondary	White paper secondary	Stainless steel
LDPE polyethylene	Glass clear	Aluminum primary
LDPE polyethylene secondary	Glass clear secondary	Aluminum secondary
PET bottle grade	Ceramic, porcelain	Chromium
PET bottle grade secondary	Concrete, not reinforced	Copper
EPS expanded polystyrene	Cement, Portland ash	Lead
EPS secondary	Sand	Magnesium
HIPS high impact polystyrene	Varnish, alkyd	Nickel
HIPS secondary	Carbon black	Palladium
PS polystyrene	Gasoline	Platinum
PS polystyrene secondary	Fuel oil	Tin
PA polyamide, nylon	Natural gas	Zinc
PC polycarbonate	Cotton fabric, pesticide free	
PP polypropylene	Polyester fabric (nylon)	**METAL PROCESSING**
PP Polypropylene secondary	Corn	Aluminum extrusion
PVC flexible polyvinyl chloride	Potato	Aluminum continuous weld
PVC rigid polyvinyl chloride	Corn starch	Aluminum MIG arc welding
PVDC, Teflon	Potato starch	Aluminum machining
SAN	Leather	Steel deep drawing, cold
PUR flexible polyurethane	Battery, alkaline	Steel cutting
PUR rigid polyurethane	Battery, lithium ion	Steel turning
Natural rubber	Integrated circuit, mixed	Steel electrode welding
Natural rubber certified		Brazing
EPDM elastomer	**TRANSPORT**	Chrome plating, electrolytic
SBR elastomer	Delivery van	Nickel plating, electrolytic
POLYMER FORMING	Truck, 16 ton	Zinc coating
Blow extrusion, PE film	Truck, 28 ton	
Blow mold	Truck, 40 ton	**LANDFILL**
Extrusion	Automobile	LDPE, HDPE
Injection mold, most plastics	Tanker ship, oceanic	PET
Injection mold PET	Freighter, inland	PP
Thermoform (vacuum)	Freighter, oceanic	HIPS, EPS, ABS
	Container ship, oceanic	PVC
POWER	Train	PVDC
Electricity	Air, continental	Paper
Photovoltaic	Air, intercontinental	Cardboard
Wind		Glass, ceramics, steel
Coal		
Gas		**INCINERATION**
Oil		PE, PP, HIPS, EPS
Wood		PET, glass
		PVC
		PVDC
		Paper
		Cardboard
		Aluminum
		Steel

Tool	Audience/User
Life Cycle Assessment Software Various commercial Life Cycle Assessment software tools are available. Review them carefully before purchasing to ensure that the tool meets your needs. ***Resources/Links*** A number of tools are identified on an EPA's Life Cycle Assessment Research website - http://www.epa.gov/ORD/NRMRL/lcaccess/index.html US Life Cycle Inventory Database - http://www.nrel.gov/lci/	***Research and development professionals***
Supplier Tools Tools to effectively manage supply chains are also necessary. These tools may include: • Management Standards applicable to suppliers and OEMs. • Substance specifications (e.g., preferences and prohibitions) incorporated into contracts • Inspection and audit programs, and certification requirements • Integration of environmental standards into QMS audits • Software programs for materials/component declarations ***Resources/Links*** ❁ Medical Device Link - http://www.devicelink.com/ ❁ Search Engine Terms: "supply chain management" and "medical device" for multiple links or "compliance" or "parts" and "database management" for various compliance management software solutions. ❁ Design News blogs (includes ones on RoHS and materials) – http://www.designnews.com/info/CA6301810.html	***Purchasing departments*** ***Auditors*** ***Suppliers*** ***OEMs***
Forum for Access to Emerging Issues and Attitudes We all tend to enter professional boxes, where we talk to similar people with similar perspectives and similar experiences. A medical device company is well served by having a process or forum for hearing of emerging issues (e.g., DEHP) and new drivers (e.g., hospital purchasing organizations) that can materially affect the marketplace in the future. ***Resources/Links*** ❁ Institute of Electrical and Electronics Engineers - http://csdl2.computer.org/persagen/DLAbsToc.jsp?resourcePath=/dl/proceedings/&toc=comp/proceedings/ecodesign/2001/1266/00/1266toc.xml ❁ MassMEDIC - http://www.massMEDIC.com	***Marketing and sales*** ***Business development*** ***Public affairs*** ***Product Designers*** ***Engineers***

- Associated Industries of Massachusetts - www.AIMNET.org
- International Society of Pharmaceutical Engineers - www.ISPE.org
- Biomedical Engineering Society - http://www.bmes.org/
- Society of Environmental Toxicology and Chemistry (SETAC) Life Cycle Assessment group - http://www.setac.org/htdocs/who_intgrp_lca.html
- IDSA Ecodesign Section - http://www.idsa.org/whatsnew/sections/ecosection/
- Journal of Sustainable Product Design - http://www.cfsd.org.uk/journal/
- Design News blogs (includes ones on RoHS and materials) – http://www.designnews.com/info/CA6301810.html

Compliance Auditing Framework

Environmental, Health and Safety Professionals Environmental Engineers

Many small and medium-sized companies can benefit from an organizational framework for conducting compliance audits. Environmental, health and safety professionals may wish to review the ASTM "Standard Guide for Environmental Compliance Performance Assessment (ASTM E 2365-05)", which provides a framework for the development of an environmental compliance assessment program. The ASTM standard establishes a tiered framework for assessing and prioritizing legal and business risks associated with environmental compliance.

An auditing tool can be a valuable complement to two other tools discussed in this Guide – an EMS and an Inventory of Applicable Requirements

Resources/Links

- ASTM Web Site - http://www.astm.org
- A Practical Guide to Toxics Use Reduction: Benefiting from TURA at your Workplace - http://www.mass.gov/envir/ota/resources/pdf/practical_guide_to_tur.pdf
- Web search results for: "environmental compliance" or "environmental auditing".

Environmental Management System (EMS)

Environmental, Health and Safety Professionals Environmental Engineers

Another tool in a manufacturer's efforts to improve environmental compliance and enhance opportunities to integrate environmental issues into design and production decision-making is an Environmental Management System (EMS). Companies with a formal Environmental Management System, such as ISO 14001, should have a policy or procedure that requires an evaluation of environmental impacts associated with the facility's products, activities and services. While this policy would not necessarily trigger a comprehensive, full-scale Life Cycle Assessment (LCA), a review of new products and production activities would be required to show evidence that the EMS is effectively implemented.

ISO 14001 registration may enhance access to overseas markets where ISO is more established. In fact, as of January 2006, 33,000 facilities in Japan and China had registered to ISO 14001

An EMS is an organizational framework designed to incorporate a continuous improvement approach into programs that impact the physical environment.

These frameworks are generally based on the "Plan, Do, Check, Act" model for coordination of organizational programs, goals and programs. EMSs are codified in a variety of international standards, including Eco-Management and Audit Scheme (EMAS), British Standard 8555, as well as ISO 14001. A number of models that are not "specifications" have also emerged, including the "Responsible Care" program of the chemical industry and various U.S. EPA models.

Terminology

According to the ISO 14001 specification, an EMS is defined as "that part of the overall management system that includes organizational structure, planning activities, responsibilities, practices, procedures, processes, and resources for developing, implementing, achieving, reviewing and maintaining the environmental policy."

An EMS framework is designed to implement the organization's policy by identifying and managing significant environmental aspects and impacts of its activities, products or services. **"Environmental aspects"** are the specific ways in which an organization affects the physical environment (e.g., generation of solid waste, air pollution, water pollution) which may be organized by environmental media, regulatory programs or organizational functions. **"Environmental impacts"**, on the other hand, are measures of how much an organization affects the environment for each aspect (e.g., x pounds of trash produced, y pounds of chemicals released to the air).

Activities in the Medical Device Sector

Most facilities involved in the manufacture of medical device parts, components or devices have strong quality management systems dictated by FDA regulations, international standards and/or customer specifications. The "Plan, Do, Check, Act" framework and experience with the QMS maxim "Say what you do" and "Do what you say" are familiar concepts to medical device manufacturers. That said, the QMS system at a facility does not often extend into the environmental functions.

Some medical device companies have implemented an EMS to improve environmental compliance programs and minimize environmental impacts. Implementation costs and resources should be minimal, as noted above, because of a "cultural" comfort with quality management systems (e.g., documents, records) and opportunities to leverage existing policies and procedures, such as corrective action processes and management review.

With the emergence of European Directives affecting product design, packaging and recycling requirements, the ISO 14001 or EMS framework can serve as a tool to assist multiple departments within a facility organize and coordinate its response to such business drivers. The EMS may also provide an opportunity for environmental issues (e.g., aspects and impacts) to be reviewed early in the product design and production engineering process. Despite this "upside," few Massachusetts medical device manufacturers have

compared to only 5,100 in the U.S.

For example, Philips' medical device facility in Andover, MA is ISO 14001 certified.

Potential Benefits of EMS :

- ***Reduced internal costs of failure***
- ***Improved operational controls***
- ***Reduced potential for compliance fines***
- ***Streamlined compliance***
- ***Integration with other programs***

An EMS is typically implemented by following these steps:

- ***Conduct a gap analysis***
- ***Review existing quality management and environmental programs***
- ***Address gaps in the system by developing or improving environmental policies and procedures***
- ***Audit system conformance and improve, as necessary***
- ***Sustain and continually improve the program***

pursued ISO 14001 registration in the absence of clear business drivers or customer demands.

Twenty-three medical device manufacturing facilities participate in EPA's Performance Track program, which requires participants to have implemented an Environmental Management System and conducted at least one round of internal reviews. DePuy Orthopaedics in New Bedford and Raynham is the only Massachusetts company. The company is also registered to ISO 14001. Other medical device companies in the EPA program include Baxter and Boston Scientific.

Resources/Links

- TURA program EMS guidance document (7/06) - http://www.mass.gov/envir/ota/resources/pdf/ems_guidance_final.pdf
- EPA Performance Track program - https://yosemite.epa.gov/opei/ptrack.nsf//faMembers?readform
- Responsible Care Program of the American Chemistry Council - http://www.responsiblecare-us.com/
- MassDEP EMS webpage - http://www.mass.gov/dep/about/priorities/overview.htm
- EPA EMS documents - http://www.epa.gov/ems/
- To order copy of ISO 14001 standards - http://webstore.ansi.org/ansidocstore/product.asp?sku=ISO+14001%3A2004

"The wave of certification is not yet crested and is increasing. We are seeing more supply chain pressures, both domestically and internationally, from the automakers, technology companies and the medical device manufacturers." James Melloni, Lead Auditor, TUV America

Roadblocks to DfE

We know what drives the design of any new medical device product:

• Functionality	• Usability
• Durability	• User needs
• Cost	• Visual appeal
• Human factors / ergonomics	• Reimbursement potential
• Relationship to other products	

Design for the Environment (DfE) considerations must vie for time and thoughtful consideration and evaluation from a product design team already burdened with considerable pressure to design products faster and cheaper.

So, what is DfE up against? Here are a few of the major hurdles that must be faced and some simple suggestions for overcoming the real or perceived barriers, based on interviews and input from product designers and business development professionals. Many of these roadblocks are interconnected. They are presented in no particular order.

Risk-Averse Industry

Because of a number of factors – 510(k) application requirements, FDA demands, the limited number of devices that may be sold, product liability concerns, health of the patient – any trade-off, such as using recycled materials or reusing a product, is likely to lose to the "safer" solution. Typical "environmental" tradeoffs are often perceived as follows:

Environmental Choice	Can be Perceived As
Considering any environmental issue	Source of delay, added expense
Using recycled materials	Lower tolerance and specifications. Potential for patient contamination
Increase energy efficiency	Higher design costs
Extend product life	Reduced sales, interference with marketing and sales business model
Design for disassembly	Higher production costs; Potential for human error = liability
Reusable	Potential for human error = liability
Biodegradability	Shorter life; lower strength

Recommendation: *First*, do your homework. Obviously, any arguments for the "environmental" choice must be overwhelmingly safe and outweigh perceived benefits of the traditional approach or material. *Second*, understand when and if

you can make an argument for an incremental environmental improvement (e.g., chemical substitution) and when and if you can challenge business assumptions (e.g., reusable component, extended product life). *Third,*, know your audience. Some hospital organizations are striving to minimize waste or move away from certain chemical materials. Customer concerns or emerging market niches should be well understood. For example, Catholic Healthcare West (CHW) announced in the winter of 2005 that it has awarded a five-year, $70 million contract to B. Braun Medical Inc. for the supply of PVC and DEHP-free intravenous (IV) bags, solutions, and tubing to the system's 40 hospitals in California, Arizona, and Nevada. More than 100 hospitals have allegedly made similar pledges. *Finally*, track medical device leaders in your niche. Braun, Baxter, Tyco, and Metadyne are but a few. Knowing that other medical device companies have committed to RoHS compliance, or material prohibitions, or recycling programs sets the stage for others to follow.

Pressure for Single Use Devices (SUDs)

In order to reduce production costs and minimize human error, medical device companies are increasingly being asked by product users or health care providers to create single use or disposable items, rather than products that can be reused or even recycled. Single-use plastic medical products now have an approximately 90% share of the medical-market poundage.

Recommendation: *First*, conduct a comprehensive or mini Life Cycle Assessment to understand the financial, liability and environmental consequences of decisions regarding disposal. Sometimes, using less of a benign material (e.g., polypropylene) and disposing of it in the trash may have reduced environmental impacts compared to a more durable item which may be reused for some period of time, or the use of a material (e.g., polyethylene) that may be more easily recycled. The only way to know for sure is to fully evaluate the scenarios. *Second*, be sure to talk to the end user – the doctor, the hospital, the patients – so that disposal, reuse or recycle options, the costs associated with these behaviors, and the infrastructure that may be necessary to support your decisions are practically understood. *Finally*, work with suppliers. For example, major plastic injection molders like Becton-Dickinson, Abbott Laboratories, Nypro, Baxter International, and Tyco International may be able to assist you in selecting materials based on criteria such as recyclability, reusability, energy input, etc.

The Move to Compartmentalize Design

There is a shift by some manufacturers to assign designers specific product components or project tasks within a larger project, rather than give an entire project to a single design team. As a result, the design task is more about functionality, fit and compliance with specs, and less about the overall product design and attributes.

Recommendation: Medical device manufacturers and product managers should clearly articulate environmental goals, as applicable, and chemical or material restrictions to ensure product compliance with applicable standards and conformance with company environmental commitments.

Inability to be there at the Beginning

Environmental, health and safety professionals, environmental engineers and even designers suggest that they often enter the product design process AFTER key fundamental decisions have been made regarding the type of device, the look, the materials, etc. These professionals are often hesitant to voice their frustrations or try to slow down the process for fear that they will be perceived as naysayers or impediments.

Recommendation: Include an environmental professional or designer with the appropriate environmental skill set on the team. Get them directly or indirectly involved at the earliest stages. Use an environmental checklist, as provided in the appendix to this Guide.

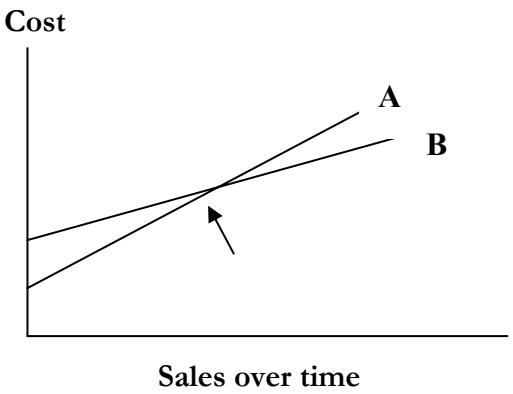
Lack of Time

In the race to bring new products to market, there may be insufficient time to effectively consider alternative materials, challenge production intentions, and evaluate design options to minimize waste or reduce toxics. Designers are most likely to influence aesthetic design decisions, and least likely to influence decisions associated with the use of materials and production processes.

Recommendation: *First*, create a DfE team or working group to support the core product team. The more players with DfE expertise or interest, the greater the chance that environmental issues will be raised in a timely manner. *Second*, utilize a framework and/or a defined process for bringing new products to market that includes an evaluation of environmental issues early in the process. For example, Tyco Healthcare and Bayer Therapeutics have developed more comprehensive checklists to be used by the product design team to ensure that environmental issues will be considered by the product design and development team. One example of such a checklist is found in Appendix B to this Guide.

Challenge Making "Long-Term" Argument

The practice of "Green Building" has made significant progress based, in part, on compelling arguments that some additional upfront capital will pay for itself over time (i.e., energy efficiency leads to reduced operating costs). While the same arguments may also be true with respect to environmental attributes of medical device products (e.g., durability, reduced waste disposal costs, energy efficient design), there is no guarantee that the medical device will be in the marketplace for an extended stay,



such that these savings will be realized. For example, in the chart above, there is no guarantee that Product B, with higher upfront costs but better margins over time, will achieve the breakeven point marked by the arrow. As a result, many companies opt for the lowest upfront capital costs.

Recommendation: The same quantitative and compelling long-term FINANCIAL arguments must be made for environmental attributes.

FDA Revalidation

Many medical device process engineers are hesitant to make significant or "threshold" changes to an FDA approved process and product unless or until the product itself is being redesigned or retooled because of other drivers that justify the investment. The concern by some companies is that almost any change – chemical substitution or minor process change – may be deemed by FDA to trigger revalidation because it is a change in procedure or because additional health and safety considerations must be evaluated.

Recommendation: *First*, review your QMS policies and procedures and determine whether they are written in such a manner as to allow the contemplated Post Approval Change, or whether they are written in a very prescriptive manner that would not allow the contemplated change without FDA review and validation. *Second*, review the change and assess whether the redesign is clearly tangential to the product (e.g., packaging that does not come into contact with the product), does not involve any portion of the product that might come into contact with patients, or utilizes a chemical or process approved for other products. Many medical device companies do make post approval process changes for environmental reasons (e.g., avoid use of regulated chemicals) without seeking FDA re-validation. Such changes will likely require a 30-day notice to the FDA as a PMA Supplement for Manufacturing Method or Process Change. *Third*, review FDA guidance documents and consider speaking with your FDA representative. The biopharma industry has successfully gained FDA policy guidance (e.g., SUPAC) with respect to post approval changes, and the medical device industry would benefit if comparable guidance was offered in addition to the guidance available about PMA supplements and amendments, which are included below. These efforts would likely benefit from the involvement of industry organizations such as MassMEDIC and AdvaMed.

The following FDA guidance documents offer insight with respect to such supplementary notification:

- FDA PMA Supplements and Amendments - http://www.fda.gov/cdrh/devadvice/pma/supplement.html#when
- 30-Day Notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes, Guidance for Industry and CDRH - http://www.fda.gov/cdrh/modact/daypmasp.html

- Deciding When to Submit a 510(k) for a Change to an Existing Device - http://www.fda.gov/cdrh/ode/510kmod.html

Guidance documents that provide some general guidance and insight include the following:

- FDA Guide to Inspections of Quality Systems (1999)
- FDA Medical Device Quality Systems Manual: A Small Entity Compliance Guide (1999) (see www.fda.gov/cdrh/dsma/gmpman.html)
- FDA Quality System Regulation Part 820 – Document and Change Control (see www.fda.gov/cdrh/qsr/09docnt.html)
- FDA Quality System Regulation Part 820 – Design Controls (see www.fda.gov/cdrh/qsr/03desgn.html)

Changes at the Manufacturing Location

Despite the concerns about FDA oversight and material substitutions, small process changes may occur at the OEM or at an overseas production facility. Such changed typically occur because of cost issues or availability of materials, but these changes may not conform with your company's environmental values or decisions.

Recommendation: Utilize effective supplier tools (see toolbox section) including audits, language in your supplier self-certifications/declarations, and appropriate contractual language to ensure that your environmental requirements are met and your environmental goals achieved.

Environmental Compliance and the Manufacture of Medical Devices

The Basic Requirements

A number of environmental compliance requirements are likely to apply to a medical device manufacturer in the Commonwealth. Some are Federal requirements, but the majority are Commonwealth of Massachusetts regulations. The primary environmental agency in Massachusetts is the Department of Environmental Protection (MassDEP), and the federal environmental agency is the Environmental Protection Agency (EPA). MassDEP's regulations are published in the Code of Massachusetts Regulations (CMR), which are available through the State House Bookstore (617-727-2834) and on the MassDEP website (http://www.mass.gov/dep). The EPA regulations are published in the Code of Federal Regulations (CFR) which is available online (www.epa.gov/epahome/cfr40toc.htm). Local communities are also likely to take an interest in a manufacturing facility by requiring compliance with a hazardous materials ordinance or flammable substance storage requirements, and with industrial wastewater requirements.

In sum, this sector appears to have a relatively "small" environmental footprint. Very few facilities appear to have large waste streams, and waste management violations have generally been

Most facilities in this sector are not faced with complicated or burdensome requirements (e.g., wastewater treatment plan; air operating permit; treatment, storage and disposal permit). Rather, they are required to comply with a reasonably straightforward set of well-known and fairly well-understood requirements.

The information and guidance on the following pages is written for the medium and small-sized manufacturers who may not have a dedicated environmental professional and/or who may benefit from some additional guidance. It is also intended to help researchers and product designers better understand the environmental compliance requirements faced by medical device manufacturers.

Minimizing environmental compliance responsibilities and obligations by avoiding certain chemicals, minimizing on-site storage, reducing wastes and conserving water and energy is smart business.

The principal objective of the information provided in this section is to help companies identify compliance landmarks and highlights, without going into great detail regarding compliance guidance. The MassDEP website, the Office of Technical Assistance staff, or your environmental consultant can assist with the nuances. Another good "starting place" for information on manufacturer's compliance requirements is the **"Catalog of Regulatory and Technical Information for Massachusetts Businesses"**, a CD produced by OTA. This CD will provide manufacturers with the information that they need to build internal regulatory capacity, to comply with state and federal environmental regulations, to reduce the use of toxic materials in their facilities, and to improve

their overall efficiency. An additional source of compliance information is the **"Index of Selected Environmental Regulations for Manufacturing Facilities: A Guide for Massachusetts Businesses by Massachusetts Businesses"**, developed by the Central Massachusetts Business Environmental Network (CMBEN) and OTA. It is available on the OTA CD mentioned above, as well as on OTA's website. Be sure to confirm or verify compliance thresholds or requirements, however, as it was developed in 2001 and there have been some regulatory changes.

This guidance does not cover all environmental requirements, but does cover the core operating requirements associated with medical device operations and activities such as prototyping, plastics and electronics manufacturing, and metal fabrication/plating. These requirements pertain to **Air Quality**, **Water**, **Wastewater**, **Waste**, and **Hazardous Materials** (including **Toxic Chemicals (TURA/TRI)**). We have put together a matrix based on a similar tool developed for the biopharma industry by the Massachusetts Biotechnology Council, which provides some core guidance. Information on OSHA requirements is included on the OTA CD described above.

In addition to this roadmap, we have included information on the following topics to assist in your efforts to comply with applicable standards:

- A list of commonly found violations
- Two compliance calendars
- A brief description of OTA compliance assistance services
- Common environmental compliance acronyms
- Contact information for key environmental organizations

Audits and Inspections

Another important tool is the use of audits or inspections. Facilities are strongly encouraged to routinely evaluate compliance with applicable regulations. The EPA and MassDEP offer certain incentives to facilities in Massachusetts that conduct a voluntary audit, discover violations and self-disclose to the applicable agency. To take advantage of these incentives, regulated entities must voluntarily discover, promptly disclose, expeditiously correct, and prevent recurrence of future environmental violations. Incentives include the potential for significant penalty reductions. Confer with legal counsel with respect to the pros and cons of self-disclosure. Information on the EPA self-disclosure policies (Small Business Policy and Audit Policy) can be found at http://www.epa.gov/compliance/incentives/index.html. Information on MassDEP's versions of these policies is at http://www.mass.gov/dep/service/enfpol.htm.

Self-Disclosure Policies:

EPA and MassDEP offer certain incentives to facilities in Massachusetts that conduct a voluntary audit, discover violations and self-disclose to the regulatory agencies.

Environmental, health and safety professionals may wish to review the ASTM "Standard Guide for Environmental Compliance Performance Assessment

(ASTM E 2365-05)", which provides a framework for the development of an environmental compliance assessment program. The ASTM standard attempts to integrate environmental compliance, environmental risk classification and business risk management for use in decision-making. It establishes a tiered framework of essential components, by asking practitioners to evaluate:

- Tier I performance standards, which looks at imminent hazards that would likely cause actual harm to human health and the environment
- Tier II performance standards, which includes an evaluation of existing or potential approvals for releases, emissions, discharges or potential releases to the environment
- Tier III performance standards, which assesses operations, maintenance, repairs and controls on emissions, discharges, releases or prevention devices
- Tier IV performance standards, including a review of records and the recordkeeping management system

Common Violations of Medical Device Manufacturers in Massachusetts

The following list of potential regulatory compliance deficiencies comes from a review of enforcement actions taken in Massachusetts and also reflects the opinions of OTA and environmental consultants to, and EH&S personnel in, the medical device sector:

Hazardous Waste

- No or inadequate container labeling
- Accumulation area not marked
- Non-notification (no generator ID number)
- No posted sign for central accumulation area
- Outdated contingency plan (LQGs)
- Exceeds generation accumulation threshold – acting out of status
- Open containers
- No emergency numbers posted
- Inadequate aisle spacing in central accumulation area
- Failing to meet emergency preparedness and response requirements
- Missing/incorrect manifest information
- Exceeding waste accumulation time limits
- Failing to retain manifest for required timeframe
- Failing to make proper hazardous waste determination
- Failing to move satellite container within 3 days of being full
- No accumulation start date on container
- No weekly inspections

Air Quality

- Failure to track/document emissions
- Operating without a plan approval
- No records to demonstrate permit compliance
- No source registration
- Fugitive emissions from open containers
- Failure to prevent air pollution
- Exceeded permit limits
- Non-compliant equipment

Industrial Wastewater

- Discharge without permit
- Exceeded permit limit
- Inadequate O&M manual
- Industrial discharge to a septic system

Toxics Use Reduction

- Failure to file TURA report
- Failed to pay fee
- Failed to submit cover sheet
- Failed to submit billing sheet

In addition to the MassDEP issues described above, deficiencies may also include the following:

- Failure to notify or submit Tier II chemical inventory information to SERC, LEPC or local fire department
- Failure to obtain a permit from the local fire department for storage of flammable liquids, solids or gases as required by the Fire Prevention Regulations
- Failure to annually update a local hazardous materials license
- Failure to file with EPA a "Non-Exposure" certification for stormwater
- Failure to develop and conform with Spill Prevention, Control, and Countermeasure Plan

Facility managers and CEOs should understand the consequences of not complying with environmental regulations. For example, under the Massachusetts Administrative Penalties Act, a failure to notify of a release of oil or hazardous materials, or to obtain a required approval, or exceeding a permit limitation can result in penalties for violations of these high priority items. Descriptions of MassDEP's recent higher level environmental enforcement actions can be found at the following website - http://www.mass.gov/dep/public/press/curren03.htm.

Compliance Calendars

Many facilities, and a number of environmental consulting firms, have developed simple to use compliance calendars and task management software tools to assist facilities in tracking and meeting their compliance management obligations. Seek assistance from your vendors/consultants. The following calendars are intended to identify potentially commonly recurring tasks, and are not meant to be all-inclusive, or applicable to all facilities.

Routine Annual Compliance

Month	Requirement	Deadline
March	Tier II Inventory (if required)	3/1
	LQGs submit biennial report to MassDEP (even numbered years)	3/1
April	Air Source Registration (if required) to MassDEP	4/15
July	Toxic Release Inventory (TRI) Form R to EPA	7/1
	Toxics Use Reduction Act (TURA) Form S to MassDEP	7/1
	TURA Plan updates (even numbered years)	7/1
September	ERP certifications to MassDEP	9/15

Recurring Compliance Calendar

Month	Requirement
Weekly	Inspection of hazardous waste satellite accumulation areas (unrecorded) and central accumulation area(s) (recorded)
Monthly	NPDES: Submit Discharge Monitoring Report (DMR) to EPA
	Tank inspections, as applicable, in accordance with UST requirements or SPCC internal standards
Bi-Monthly	Wastewater Discharge Monitoring Report, per Publicly Owned Treatment Works (POTW)
Quarterly	Wastewater Discharge Monitoring Report, per POTW
	Hazardous wastes shipment for Large Quantity Generator (90 days)
Semi-Annual	Wastewater Discharge Monitoring Report, per POTW
	Hazardous wastes shipment for Small Quantity Generator (180 days)
Annual	Tier II Inventory
	Air Source Registration for major facilities, to MassDEP
	Universal wastes shipment
	Flammable Substance and/or Hazardous Material Permit
Biennial	LQGs submit biennial report to MassDEP (even numbered years)
Triennial	Air Source registration for smaller facilities, to MassDEP
5 Years	Renewal of NPDES Storm Water General Permit
	Renewal of NPDES Storm Water No Exposure Certification (if applicable)

Environmental Operating Requirements Applicable To Medical Device Facilities in Massachusetts

The matrix[1] below identifies environmental "operating" requirements that are potentially applicable to medical device manufacturing facilities in Massachusetts. This matrix tool is designed to provide staff with environmental responsibilities at medical device manufacturing facilities, as well as researchers and product developers in the sector, with a working sense of certain fundamental environmental permits and operating requirements. The information in the matrix assumes that the user is a small or mid-sized company, and is current as of the date of this document.

This tool is not designed to identify all relevant and applicable requirements, or provide comprehensive guidance. ***Seek professional and legal counsel to understand fully the applicable requirements for your specific facility or site.***

Below are categories for further information about the applicable requirements. **Click on a specific topic to go to that section of the matrix.**

(a) The summaries of these regulations will be added in early 2007 when their review is completed.

For each topic, additional information is provided such as:

- Key issues associated with the type of medical device operations and activities, such as prototyping, plastics and electronics manufacturing, or metal fabrication/plating
- Relationship of these operational requirements to Pollution Prevention (P2) and Design for the Environment (DfE)
- Common compliance issues or challenges faced by companies
- Key records to retain to demonstrate compliance
- Web Resources or Search Terms

Be sure to review the section entitled "Environmental Management Systems" (EMS) in the DfE Toolbox section of this Guide. An EMS is an important tool in your efforts to improvement environmental compliance and enhances opportunities to integrate environmental issues into product and business decision-making.

[1] This matrix has been modified from a matrix developed by the Massachusetts Biotechnology Council for biopharma facilities.

Hazardous Materials	Applicability To Types Of Operations
Hazardous Chemical Storage Per State Fire Prevention regulations, permits from the local fire department may be required for the storage of certain flammable substances, hazardous chemicals or for above-ground storage tanks with a capacity of greater than 500 gallons.	**Basic Research, Model Building or Prototype Operations** Use a wide variety of chemicals, including flammable solvents, cutting oils, acids and bases – typically in containers less than 1 gallon. **Plastics Operations** Likely to use larger quantities of certain chemicals, which may include epoxies, lubricants, blowing and foaming agents, phenolic compounds, polyurethanes, polyesters or polyethylene, which may be stored in drums or process vessels. Chemicals may be stored in 55-gallon drums or larger vessels. **Electronics Operations** Likely to use larger quantities of certain chemicals, such as solvents, alkaline cleaning solutions, acids, resists, lead solder, flux, developing solutions and etching materials which may be stored in drums or process vessels. Chemicals may be stored in 55-gallon drums or larger vessels. **Metal Plating/Fabrication Operations** Likely to use larger quantities of certain chemicals, such as oils, degreasing and cleaning solvents, acids, alkalis, paints, heavy metal-bearing solutions and cyanide- bearing solutions which may be stored in drums or process vessels. Chemicals may be stored in 55-gallon drums or larger vessels. **Assembly** Likely to use solvents or cleaners prior to assembly.

Relationship to P2/DfE	• Limit use of flammable materials or hazardous chemicals, to the extent practicable, through toxic material substitution and inventory control • Identify goals for priority toxics to reduce or eliminate • Institute review procedures to ensure that EH&S professional or environmental engineer evaluates chemicals or byproducts associated with the manufacture of any new medical devices.
Further Guidance or Common Compliance Challenges	Common compliance issues: • Failure to file initial permit or update permit on annual basis
Compliance Records	• Current Permits • Most recent application for permits, including any supporting information • Inventory data
Web Resources and Key Search Terms	➢ **State Fire Marshal forms - http://www.mass.gov/dfs/osfm/forms/index.htm**

Hazardous Materials	Applicability To Types Of Operations
Flammable Substance Storage A flammable storage permit is required from the head of the local fire department. Local thresholds vary, but a permit is likely for storage of a Class I liquid. A license for flammable storage from the local licensing authority may also be required per State Fire Prevention regulations (527 CMR 14.00). (A flammable liquid is known as a Class I liquid, and is any liquid having a flash point below 100o F and a vapor pressure not exceeding 40 psia at 100o F. Class I liquids are divided into 3 classifications – IA, IB, and IC)	**Basic Research, Model Building or Prototype Operations** Storage and use requirements dictated by State Board of Fire Prevention, building codes and NFPA standards. Typically, containers used are less than 1-gallon and stored in flammable storage cabinets and flammable safety containers **Manufacturing Operations** Flammables may be stored in 55-gallon drums. Facility may require flammable storage room with specific protection, such as spill containment, grounding, etc. Flammables may also be stored in totes, larger vessels, a dedicated room or in bulk tanks. **Assembly** Flammable storage is likely to be limited, but may include 55-gallon drums of hazardous chemicals used to clean or disinfect parts prior to final assembly.

Relationship to P2/DfE	Limit use of flammable materials, to the extent practicable, through toxic material substitution and inventory control
Further Guidance or Common Compliance Challenges	Common compliance issues: Failure to file initial permit or update permit on annual basis
Compliance Records	**Current Permits** Most recent application for permit, including any supporting information Inventory data
Web Resources and Key Search Terms	➢ State Fire Marshal forms - http://www.mass.gov/dfs/osfm/forms/index.htm ➢ State Fire Prevention regulations (527 CMR 14.00) - http://www.mass.gov/Eeops/docs/dfs/osfm/cmr/527014.pdf ➢ Department of Fire Services - http://www.mass.gov/dfs/osfm/fireprevention/index.shtm

Hazardous Materials	Applicability To Types Of Operations
Emergency Planning For Hazmat Incident No state permit or license required. EPCRA requirements: Sections 301 – 303 (Emergency Planning): pertains to EHS onsite above Threshold Planning Quantities (TPQ). Requires development of Emergency Response Plan and submittal to LEPC. Section 304 (Emergency Notification): Facilities must immediately notify the LEPC and the SERC if there is a release into the environment of a hazardous substance that is equal to or exceeds the minimum reportable quantity (RQ) set in the regulations. Covers the 356 EHS as well as the more than 700 hazardous substances subject to the emergency notification requirements under CERCLA Section 103(a)(40 CFR 302.4). A written follow-up notice must be submitted to the SERC and LEPC as soon as practicable after the release. CERCLA spills must also be reported to the National Response Center at (800) 424-8802. Section 311 (MSDS submission): facilities that have MSDSs for chemicals held above certain quantities must submit either copies of their MSDSs or a list of MSDS chemicals to the SERC, LEPC, and local fire department. Section 312 (Emergency and Hazardous Chemical Inventory reporting): facilities that need to report under EPCRA section 311 must also submit an annual inventory report (Tier II) for the same chemicals. This inventory report must be submitted to the SERC, LEPC and local fire department by March 1 of each year. Other: the release of any of 77 toxic substances and 63 flammable substances above Threshold Quantities are subject to the accident prevention provisions of Section 112(r) of the Clean Air Act. The need for an OSHA Emergency Action Plan is triggered by the use of hazardous chemicals. Development of a Spill Plan (SPCC) is required if total oil storage exceeds 1,320 gallons. This is an EPA requirement described at 40 CFR 112. In addition, Massachusetts General Law Chapter 21E	**Basic Research, Model Building or Prototype Operations** Reporting or notification is unlikely because quantities of chemicals used are minimal. **Plastics Operations** Some reporting is likely because of use of fuel oil for heating, EHS (e.g., chlorine) stored above TPQ, or additive chemicals such as blowing or foaming agents stored above 10,000 pounds. **Electronics Operations** Some reporting is likely because of use of fuel oil for heating, EHS (e.g., ammonia) stored above TPQ, or storage above 10,000 pounds for solvents, acids or metals. **Metal Plating/Fabrication Operations** Some reporting is likely because of use of fuel oil for heating, EHS (e.g., cyanide) stored above TPQ, or storage above 10,000 pounds for solvents, acids, or metal plating solutions. Assembly Requirements are unlikely to be triggered, except Tier II reporting requirements for storage of fuel oil.

and the Massachusetts Contingency plan require notification of releases of oil or hazardous materials above certain quantities or when detected above reportable concentrations.	
Relationship to P2/DfE	Opportunities to implement toxics use reduction, and lean manufacturing to reduce chemical usage or avoid the use of extremely hazardous substances.
Further Guidance or Common Compliance Challenges	**Common compliance issues:** ● Failure to submit initial notification for EHS substances above prescribed thresholds or hazardous substances manufactured, used or otherwise process in excess of 10,000 pounds ● Failure to include all chemicals on-site that exceed applicable thresholds ● Failure to keep SPCC plan up-to-date and implement training and inspection provisions ● Fuel oil in UST is exempt, if comply with applicable UST requirements.
Compliance Records	Notification to SERC, LEPC, and Local Fire Department for chemicals that exceed TPQ for EHS or 10,000 pound threshold for OSHA hazardous chemicals. Notification of storage of EHS above threshold Tier II Reports and supporting data SPCC Plan and records of implementation (e.g., inspection records, training)
Web Resources and Key Search Terms	➢ EPA EPCRA information - http://yosemite.epa.gov/oswer/ceppoweb.nsf/content/EPCRA.htm?OpenDocument ➢ EPCRA fact sheet - http://yosemite.epa.gov/oswer/ceppoweb.nsf/vwResourcesByFilename/epcra.pdf/$File/epcra.pdf ➢ List of chemicals subject to EPCRA and Section 112(r) of CAA (List of Lists) - http://yosemite.epa.gov/oswer/ceppoweb.nsf/vwResourcesByFilename/title3.pdf/$File/title3.pdf ➢ Tier II software - http://www.epa.gov/NE/enforcement/epcra/software.html ➢ OSHA Emergency Action Plans - http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9726 ➢ Massachusetts Contingency plan requirements – http://www.mass.gov/dep/cleanup/proces01.htm ➢ OTA Environmental Quality Management article (integrating emergency planning) - http://www.mass.gov/envir/ota/publications/pdf/preventive_preparedness_eqm_article_reibstein.pdf

Hazardous Materials	Applicability To Types Of Operations
Toxic Chemicals **TRI and TURA:** Medical device manufacturing facilities with 10 or more full-time employees that manufacture, process, or otherwise use a Toxics Release Inventory (TRI) listed chemical above threshold quantities must comply with EPA's Toxics Release Inventory program with annual reporting of a Form R. The threshold quantities are manufacturing or processing > 25,000 pounds of a listed chemical, or otherwise using > 10,000 pounds; the thresholds for PBTs are significantly lower. The Form R must be submitted to EPA and MassDEP by July 1 and cover releases and other waste management of toxic chemicals that occurred during the previous calendar year. These facilities – as well as other facilities that manufacture, process, or otherwise use a Massachusetts Toxics Use Reduction Act (TURA) listed chemical at or above the threshold quantities – must submit annually (by July 1) a report form (Form S) to the MassDEP and pay an annual toxics use fee. The Form S identifies the quantity of each listed chemical used, generated as a byproduct, and shipped as part of a finished product. TURA filers are also required to prepare a toxics use reduction plan. The TURA Plan must be updated every two years and signed by a state-certified Toxics Use Reduction planner (TURP). The 2006 TURA revisions lowered reporting thresholds for chemicals designated as Higher Hazard. They also provide alternative planning options after a company has completed 1 toxics use reduction plan and 2 plan updates: a resource conservation plan for energy, water, or materials use (allowed every other planning cycle); or an EMS in lieu of a TUR plan (provided reportable toxics are addressed in the EMS). **Toxic Substances Control Act (TSCA):** The importation and/or manufacture of new chemicals for commercial purposes requires a Premanufacturing Notice to be submitted to EPA. **OSHA:** Sets chemical exposure levels and monitoring	**Basic Research, Model Building or Prototype Operations** Unlikely to use sufficient quantity of chemicals to be covered by these requirements. **Manufacturing Operations** Facilities may exceed thresholds. Examples may include solvents, volatile organic compounds, DEHP, or toxic metals.

requirements. Recordkeeping of chemical injuries is required. Facilities with hazardous chemicals are required to conduct hazard communication training.	
Relationship to P2/DfE	Companies covered by TURA are required, by law, to evaluate opportunities to minimize the use of listed chemicals and develop and maintain plans to reduce usage and releases of these chemicals. For example, a number of large medical device manufacturers have been able to make process changes that avoided or reduced chemical usage so that they no longer file reports. Examples include companies that formerly reported for lead, Freon 113, cobalt and chromium. Process modifications or chemical substitutions may, however, be thwarted by concerns that such changes will trigger FDA submittal/approvals. Such decisions will be based on the extent of the change, the language in the QMS/GMP procedures and the component(s) affected. Opportunities to limit chemicals typical of plating and coating operations may apply to hydrochloric acid, methyl ethyl ketone, nitrate compounds, potassium hydroxide, silver, toluene, vinyl acetate, xylene and zinc. Many companies are currently evaluating alternatives to DEHP, a TURA listed chemical that is commonly used as an additive to plastics. Alternatives reviewed by TURI include Trioctyl trimellitate (TOTM), Di (2-ethylhexyl) adipate (DEHA), Butyryl trihexyl citrate (BTHC), Di (isononyl) cyclohexane-1,2-dicarboxylate (DINCH) and Di isononyl phthalate (DINP). Additionally, the Toxics Use Reduction Institute (TURI) has conducted the "Five Chemicals Study" which explores alternatives to DEHP, as well as lead, formaldehyde, perchloroethylene and chromium (VI).
Further Guidance or Common Compliance Challenges	Common Compliance Issues - • Failure to file TRI or TURA Report • Failure to pay TURA fee • Failure to prepare/update TURA plan
Compliance Records	• TRI Report and backup data • TURA Report and backup data • Current TURA Plan • OSHA – records of chemical injuries
Web Resources and Key Search Terms	➢ EPA TRI site - http://www.epa.gov/tri ➢ List of TRI Chemicals - http://www.epa.gov/tri/chemical/index.htm ➢ EPA TRI guidance - http://www.epa.gov/tri/report/index.htm ➢ MassDEP TURA home page – http://www.mass.gov/dep/toxics/toxicsus.htm ➢ Summary of TURA 2006 revisions - http://www.mass.gov/envir/ota/resources/tur.htm ➢ MassDEP TURA regulations - http://www.mass.gov/dep/toxics/laws/regulati.htm ➢ MassDEP TURA forms - http://www.mass.gov/dep/toxics/approvals/turforms.htm ➢ MassDEP TURA guidance (reporting, planning) - http://www.mass.gov/dep/toxics/laws/policies.htm

	➢ OTA compliance assistance (Right From the Start) - http://www.mass.gov/envir/ota/programs/right_start.htm ➢ OTA fact sheets (e.g., reporting PBTs) - http://www.mass.gov/envir/ota/publications/fact_sheets.htm ➢ OTA onsite assistance (request site visit) - http://www.mass.gov/envir/ota/programs/onsite_assist.htm ➢ TURI Five Chemical Study - http://www.turi.org/content/content/view/full/2739/ ➢ EPA TSCA website - http://www.epa.gov/region5/defs/html/tsca.htm ➢ OSHA website - http://www.osha.gov/index.html ➢ OSHA HAZCOM website - http://www.osha.gov/SLTC/hazardcommunications/index.html

Air Emissions	Applicability To Types Of Operations
Pre-Construction notification form, BWP AQ 06, may be required to be submitted to the MassDEP prior to construction or demolition. **Combustion Equipment (Boilers, Stand-By Generators)** A plan approval (permit) is required for boilers with heat inputs larger than the applicable thresholds in the regulations. The level of review is dependent on the fuel of use and the heat input of the individual boiler. Boilers utilizing distillate oil or natural gas that are smaller than 10 million (MM) Btu per hour heat input are exempt from pre-construction plan review. When not located at a facility holding an operating permit, a new boiler(s) with a heat input rating between 10 MM and 40 MM BTU/hour is subject to the Environmental Results Program for boilers, where the owner/operator self certifies to MassDEP that the boiler was installed and is operated in compliance with the regulation. The permit and operating requirements for emergency generators are contained in the air regulations at 310 CMR 7.26(40) through (44).	**Applicable to all facilities** **Basic Research, Model Building or Prototype Operations** These facilities have boilers and may have emergency generators. Permits are not typically required, provided boilers and generators are below permitting thresholds. **Manufacturing and Assembly Operations** Self-certification may be required as boiler and generator systems increase in size to meet power requirements. Large facilities may require permits if boilers exceed 10 MM BTU/hour.

Relationship to P2/DfE	• Install energy efficient boilers and furnaces • Design the building and processes to conserve fuel usage • Explore daylighting, use of renewable energies
Further Guidance or Common Compliance Challenges	• See 310 CMR 7.02, 7.04, & 7.05 (Fuel Burning), 310 CMR 7.26, and 310 CMR 70.00 for the ERP Program. • Common compliance issues - • Failure to obtain permit or submit self-certification • Failure to log emergency generator usage
Record Retention	• Fuel usage information • Specifications on boilers, emergency generators • Emergency generator log • ERP compliance certification • Annual testing/maintenance checkup
Web Resources and Key Search Terms	➢ MassDEP air regulations - http://www.mass.gov/dep/air/laws/regulati.htm ➢ MassDEP air quality forms - http://www.mass.gov/dep/air/approvals/aqforms.htm ➢ MassDEP Environmental Results Program for Boilers - http://www.mass.gov/dep/service/online/erpforms.htm#boilers ➢ Energy efficiency - http://www.eere.energy.gov/industry/ and

	http://www.mass.gov/envir/ota/resources/energy_conserv.htm ➢ Energy efficiency – boilers and furnaces http://www.energystar.gov/ ➢ Renewable energy - http://www.mtpc.org/

Air Emissions	Applicability To Types Of Operations
Non-Combustion Emissions A plan approval is required for greater than 1 ton per year of air emissions (including fugitive emissions) from emission units other than combustion equipment. The one-ton per year threshold is based on Potential to Emit (PTE). Some facilities, when you aggregate their emissions from process and combustion related operations, may emit air pollutants (VOC, NOx, SOx, CO, particulate matter (PM), lead or hazardous air pollutants) exceeding the thresholds for the federally required operating permit program, 310 CMR 7.00: Appendix C. An operating permit is required for: >50 tpy VOC or NOx >100 tpy CO, SO2, PM >10 tpy for any single HAP >25 tpy for a combination of HAPs Medical device facilities are more likely to require a plan review under 310 CMR 7.02 for emissions of VOCs and/or other Hazardous Air Pollutants (HAPs) or elect to comply with 310 CMR 7.03(25). Many medical device facilities in Massachusetts currently operate under Restricted Emissions Status (RES) permits to avoid being subject to the operating permit program. Facilities emitting VOCs may also need to comply with the Reasonably Available Control Technology (RACT) requirements in 310 CMR 7.18. Facilities emitting HAPs may be subject to a NESHAP (MACT standard) defined at 40 CFR Part63.	**Basic Research, Model Building or Prototype Operations** Emissions likely to be less than 1 ton. **Manufacturing Operations** Facilities may exceed criteria thresholds. VOC is most likely candidate. Permitting requirements will apply to total emissions from all sources of pollutants. **Electronics Operations & Metal Plating/Fabrication Operations** May need to comply with the MACT standard for Halogenated Solvent Cleaning if the solvent used is regulated by the standard.

Relationship to P2/DfE	A number of large medical device manufacturers have been able to make process changes that avoided or reduced chemical usage which have minimized air pollutants. A number of these facilities have set goals for further reduction of solvents over the next 3-6 years. Process modifications or chemical substitutions may, however, be thwarted by concerns that such changes will trigger FDA submittal/approvals. Such decisions will be based on the extent of the change, the language in the QMS/GMP procedures and the component(s) affected.
Further Guidance or Common Compliance	**Guidance** Owners/Operators wishing to limit their facility's emissions to below major source or RACT applicability for VOCs may obtain Restricted Emissions Status (RES) and avoid being a major facility.

Challenges	310 CMR 7.03 establishes a number of Plan Approval Exemptions (e.g., spray booth operations, Biotechnology surface disinfection) which you may elect to comply with in lieu of applying for a plan approval under 310 CMR 7.02. Medical device companies producing a FDA approved product may be eligible for an exemption from permit requirements if: the total facility-wide actual emissions, including new or modified surface disinfection processes do not exceed 15 tons of VOCs per 12-month rolling period (this limit includes all process operations at the facility and VOC emissions shall not exceed 2.5 tons per calendar month); total HAP emissions shall not exceed 9 tons of any single HAP per 12-month rolling period nor 15 tons of any combination of HAPs. If emissions exceed these thresholds, then a comprehensive plan approval must be sought. Most medical device facilities will likely have to submit source registration information every three years. Facilities that may be subject to the requirements of source registration information annually include: a facility subject to the operating permit program, 310 CMR 7.00: Appendix C; a facility operating under a RES pursuant to 310 CMR 7.02(9); a facility with actual emissions of NOx or VOC equal to or greater than 25 tons per year; a facility subject to a NESHAP or a MACT standard defined at 40 CFR Part 61 and Part 63; or a facility required by a condition of its plan approval. OTA has developed several software tools to help companies comply with air quality requirements. RUNVOC performs the necessary calculations and generates a completed SFP1 form, as required for MassDEP Limited Plan Approval (LPA) or Comprehensive Plan Approval (CPA). RECORDS is a spreadsheet for tracking the usage of chemicals for regulatory compliance and/or internal record keeping. DEGREASE is a spreadsheet to document actual emissions from degreasers regulated under the U.S. EPA NESHAP for Halogenated Solvent Cleaning.
Compliance Records	● Permit ● Chemical usage, including compositional information (e.g., % VOC) for VOCs and HAPs ● Sampling and analysis ● Equipment and pollution control maintenance ● Reports to state
Web Resources and Key Search Terms	➢ MassDEP air regulations - http://www.mass.gov/dep/air/laws/regulati.htm ➢ MassDEP air quality forms - http://www.mass.gov/dep/air/approvals/aqforms.htm ➢ MassDEP source registration - http://www.mass.gov/dep/service/compliance/sr.htm ➢ MassDEP Compliance Assistance - http://www.mass.gov/dep/air/complian.htm ➢ EPA Air Toxics (NESHAPS) information - http://www.epa.gov/ttn/atw/eparules.html ➢ OTA software tools (RUNVOC, RECORDS, DEGREASE) - http://www.mass.gov/envir/ota/software/software.htm

Air Emissions	Applicability To Types Of Operations
Nuisance (Odor, Dust, Noise) And Visible Emissions There are regulatory prohibitions against creating nuisance conditions and visible emissions that apply to all facilities at all stages. Local Boards of Health can also act against a public nuisance. Miscellaneous requirements: Handling of asbestos, especially during building renovations, is regulated by the state and must be undertaken by licensed individuals. Ride share provisions require facilities to file an annual plan for reducing commuter trips of their employees.	**Basic Research, Model Building or Prototype Operations** Unlikely to be a problem although active model or prototype shops may create dust and noise. **Manufacturing and Assembly Operations** Roof top mechanicals and emergency generators have nuisance potential. Locate equipment in the facility so as to minimize potential for nuisance; equipment may be enclosed with sound attenuation. Boilers can be sources of visible emissions.

Relationship to P2/DfE	Not generally applicable. However, DePuy, for example, installed acoustic foam to blast cabinet rear doors and installed noise baffle system on coolant pumps and installed acoustic curtains around lathing equipment to minimize noise within the plant in New Bedford.
Further Guidance or Common Compliance Challenges	Limited issues
Compliance Records	● Maintenance records ● Emissions testing or noise sampling ● Citizen or community complaints and response/corrective action
Web Resources and Key Search Terms	➢ MassDEP regulations (visible emissions) – http://www.mass.gov/dep/air/laws/7b.htm#06 ➢ MassDEP regulations (dust, odor) – http://www.mass.gov/dep/air/laws/7b.htm#09 ➢ MassDEP regulations (noise) – http://www.mass.gov/dep/air/laws/7b.htm#10

Waste	Applicability To Types Of Operations
Hazardous Waste According to MassDEP, the medical device sector is characterized by a wide variety of waste streams, including waste oil which is a hazardous waste in Massachusetts. If applicable, register with the MassDEP and/or the EPA as a generator of hazardous waste. The quantity of hazardous waste or waste oil generated monthly and total quantity of waste accumulated will determine generator status and management requirements. The three categories of generator status (VSQG, SQG, LQG) are defined to the right under "Applicability to Types of Operations". Elementary neutralization of aqueous corrosive hazardous waste is allowed per MassDEP's 11/4/05 amendments to the hazardous waste regulations (see 310 CMR 30.1100). Other treatment of hazardous waste, however, is generally prohibited without a license in Massachusetts.	**Basic Research, Model Building or Prototype Operations** Likely to be a Very Small Quantity Generator (VSQG) or possibly a Small Quantity Generator (SQG). A VSQG generates less than 100 kilograms (~25 gallons) per month and no "acutely hazardous wastes." A SQG generates more than 25 gallons but less than 250 gallons (~1,000 kilograms) per month or acutely hazardous waste (less than 2.2 pounds per month). Additional management requirements apply to an SQG. **Plastics Operations** Facility likely to be an SQG and must meet additional container management and accumulation requirements. Large facilities may be subject to Large Quantity Generator (LQG) regulations. A LQG generates greater than 1000 kilograms (~250 gallons) or greater than 2.2 pounds of acute hazardous waste per month. Additional management, emergency preparedness and response, training and reporting requirements apply. Typical wastes may include solvents, oils and wastes containing heavy metals. **Electronics Operations** Facility likely to be an SQG or LQG for hazardous waste or waste oil. Typical wastes may include solvents, ignitables, epoxies, sludges, acids, metals and etching wastes. **Metal Plating/Fabrication Operations** Facility likely to be an SQG or LQG for hazardous waste or waste oil. Typical wastes may include solvents, ignitables, solvent still-bottoms, sludges, metal- and cyanide-bearing wastes, and reactive wastes. **Assembly** Unlikely to generate hazardous waste, unless waste solvents are generated from product or component piece cleaning.

Relationship to P2/DfE	Direct relationship between DfE, P2 and lean manufacturing that reduces the generation of hazardous waste.
Further Guidance or Common Compliance Challenges	**Further Guidance** 1. Know your wastes. 2. Determine your generator status for hazardous waste and waste oil. 3. Notify MassDEP and/or register to obtain a generator identification number. And notify the MassDEP if your generator status changes. 4. For all hazardous wastes – (1) label each container as "Hazardous Waste," with the name of the waste (e.g., waste acid), the hazard (e.g., ignitable, toxic, corrosive, reactive), and the date accumulation began; and (2) keep containers closed except when adding or removing wastes. 5. Identify satellite accumulation areas and main hazardous waste storage areas and meet appropriate standards for each: 6. Hazardous Waste Storage Area – (1) store on impervious floor; (2) Identify area and post sign; (3) Meet NFPA standards for flammable storage; (4) Install berm area if near open floor drain; (5) Label and date all drums, when filling begins or container is placed in area; (6) Inspect drums weekly and record inspection; (7) Meet emergency preparedness and response standards, such as posting of emergency information at nearby phone or communication device, posting of evacuation maps and emergency response equipment 7. Satellite Accumulation Area – (1) Locate at or near the point of generation; (2) Store on impervious surface; (3) Limit accumulation to 55-gallons per waste container; (4) Limit accumulation to one container per wastestream; (5) Label all containers; (6) Date when container is filled or when moved from accumulation area to waste storage area; and (7) Move to central storage area within 3 days of container becoming full. 8. Generator Accumulation limits are as follows: - LQG – 90 days from date on drum or tank (no quantity limit). - SQG – 180 days from date on drum or tank (1,650 gallons total in tanks or drums). - VSQG – No time limit, but accumulation limited to 275 gallons. 9. Do not treat hazardous waste without a permit unless the treatment is elementary neutralization of aqueous corrosive hazardous waste (per MassDEP's 11/4/05 Elementary Neutralization amendments). 10. Develop and comply with a written emergency response contingency plan, if your facility is a LQG. 11. Maintain all records for a minimum of three years. **A number of paperwork or administrative deficiencies are often noted during agency inspections or self-audits. See the list of common violations in this section for further information.**
Compliance Records	● Generator notification/registration ● Waste determination/analysis ● Training plans, as applicable ● Weekly inspections of main hazardous waste storage areas ● Contingency plan, for Large Quantity Generators (LQGs) ● Manifests and Land Disposal Restriction (LDR) paperwork ● Biennial reports (LQGs)
Web Resources and	➢ MassDEP hazardous waste regulations -

Key Search Terms	http://www.mass.gov/dep/recycle/laws/regulati.htm#hw ➢ Generator requirements - http://www.mass.gov/dep/recycle/hazardous/generati.htm ➢ HW policies and guidance - http://www.mass.gov/dep/recycle/laws/policies.htm ➢ MassDEP SQG Guidance document - http://www.mass.gov/dep/recycle/laws/sqgsum.pdf ➢ Compliance assistance resources (fact sheets) - http://www.mass.gov/dep/recycle/compliance/factguid.htm#hwm ➢ EPA RCRA Orientation Manual (3/06) - http://www.epa.gov/epaoswer/general/orientat/ ➢ ERP guidance for certain industries (not medical devices) - http://www.mass.gov/dep/service/online/erpforms.htm ➢ DOT Hazardous Materials Transportation (HMT) Security information - http://hazmat.dot.gov/riskmgmt/hmt/hmt_security.htm

Waste	Applicability To Types Of Operations
Universal Wastes/Cathode Ray Tubes Universal wastes include batteries, pesticides, thermostats, mercury-containing devices, and mercury-containing lamps (e.g., fluorescent lamps). These spent or unwanted materials must be separated, containers labeled and shipped off-site every 12 months. Cathode ray tubes (CRTs), such as computer monitors, are prohibited from solid waste disposal.	**Applicable to all Facilities** Likely to generate small quantities of these wastes. Universal wastes must be shipped off-site within 12 months of being identified as a universal waste. CRTs are not required to be disposed of annually.

Relationship to P2/DfE	• Energy conservation/lighting audits • Use energy conserving lamps (e.g., compact fluorescent, LED) • Collect and recycle electronic equipment
Further Guidance or Common Compliance Challenges	• Failure to designate collection area • Failure to properly label all containers of universal wastes • Disposal of florescent lamps, a universal waste, is a common violation in office buildings.
Compliance Records	Waste disposal manifest/shipping form
Web Resources and Key Search Terms	➢ **MassDEP hazardous waste regulations - http://www.mass.gov/dep/recycle/laws/regulati.htm#hw** ➢ **MassDEP fact sheet (universal waste rule) - http://www.mass.gov/dep/recycle/hazardous/univrule.pdf** ➢ **MassDEP electronics recycling information - http://www.mass.gov/dep/recycle/reduce/electron.htm** ➢ **CRT recycling - http://www.wastecap.org/wastecap/commodities/crt/crt.htm**

Environmental Acronyms

AST	Aboveground Storage Tank
BACT	Best Available Control Technology
BMPs	Best Management Practices
CAA	Clean Air Act
C/D	Construction/Demolition
CESQG	Conditionally Exempt Small Quantity Generator (Hazardous Waste)
CFR	Code of Federal Regulations
CMR	Code of Massachusetts Regulations
CO	Carbon Monoxide
CPA	Comprehensive Plan Approval (Air)
CWA	Clean Water Act
DEHP	Di(2-ethylhexyl) phthalate (CAS No [117-81-7])
DFA	Department of Food and Agriculture (Massachusetts)
DfE	Design for the Environment
DMR	Discharge Monitoring Report (wastewater)
DPH	Department of Public Health
EIR	Environmental Impact Report
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right to Know Act
ERP	Environmental Results Program (Massachusetts)
ES	Emissions Statement
HAPs	Hazardous Air Pollutants
HAZWOPER	Hazardous waste operations
HOC	Halogenated Organic Compound
ICP	Integrated Contingency Plan
LEPC	Local Emergency Planning Committee
LQG	Large Quantity Generator
LPA	Limited Plan Approval (Air)
LSP	Licensed Site Professional
MACT	Maximum Achievable Control Technology
MassDEP	Massachusetts Department of Environmental Protection
MCP	Massachusetts Contingency Plan
MEPA	Massachusetts Environmental Policy Act
NESHAPS	National Emission Standards for Hazardous Air Pollutants
NOx	Nitrogen Oxides
NPDES	National Pollutant Discharge and Elimination Systems (Water)
NSPS	New Source Performance Standards (Air)
P2	Pollution Prevention
PBTs	Persistent Bioaccumulative Toxics
PE	Professional Engineer
PM	Particulate Matter
POTW	Publicly Owned Treatment Works (Wastewater)
Ppb, ppm	Parts per billion, parts per million
PTE	Potential to Emit (Air)
PVC	Polyvinyl Chloride
RACT	Reasonably Available Control Technology

Environmental Acronyms (Cont'd)

RCRA	Resource Conservation and Recovery Act
RES	Restricted Emissions Status (Air)
SDWA	Safe Drinking Water Act
SSEIS	Stationary Source Emissions Inventory System
SEP	Supplemental Environmental Project
SERC	State Emergency Response Commission
SIU	Significant Industrial User (Water)
SO_2	Sulfur Dioxide
SPCC	Spill, Prevention, Control and Countermeasure
SQG	Small Quantity Generator (Hazardous Waste)
tpy	tons per year
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act
TURP	Toxics Use Reduction Planner
UIC	Underground Injection Control
UST	Underground Storage Tank
VOC	Volatile Organic Compound
VSQG	Very Small Quantity Generator (Hazardous waste)
WWTF	Waste Water Treatment Facility

Environmental Compliance Contact Information

Massachusetts Department of Environmental Protection (MassDEP)
Web site: http://www.mass.gov/dep
Boston Office: 617-292-5500
MassDEP InfoLine: 800-462-0444
Spill Reporting Hotline: 888-304-1133, toll-free
MA Contingency Plan Hotline: 617-338-2255
Western Regional Office (Springfield): 413-784-1100
Central Regional Office (Worcester): 508-792-7683
Northeast Regional Office (Wilmington): 978-661-7677
Southeast Regional Office (Lakeville): 508-946-2714

Massachusetts Department of Public Health
Web site: http://www.mass.gov/dph
Boston: 617-624-6000

Massachusetts Department of Agricultural Resources
Web site: http://www.mass.gov/agr
Pesticide Bureau (Boston): 617-626-1700

Massachusetts Division of Occupational Safety
Web site: http://www.mass.gov/dos
OSHA Consultation Service (West Newton): 617-969-7177

Massachusetts Department of Fish and Game
Web site: http://www.mass.gov/dfwele
Boston: 617-626-1500

Massachusetts Office of Technical Assistance
Web site: http://www.mass.gov/envir/ota
Boston: 617- 626-1060

Massachusetts State Fire Marshall's Office - Department of Fire Services
Web site: http://www.mass.gov/dfs/osfm/exec/index.htm
Stow: 978-567-3100

United States Environmental Protection Agency
Web site: http://www.epa.gov and for the region http://www.epa.gov/region01/
EPA New England (Boston): 617-918-1111
New England Environmental Assistance Team Hotline: 800-906-3328
Emergency Planning and Community Right to Know Act Hotline: 800-535-0202
National Response Team: 800-424-8802

United States Occupational Health and Safety Administration (OSHA)
OSHA web site: www.osha.gov
Boston: 617-565-9860

Case Studies

The following case studies are designed to "illustrate" a Design for Environment (DfE) concept or describe a product that may reduce environmental impacts because of its design, manufacturing or use. OTA does not endorse any of these products, has not tested them and does not take responsibility for the accuracy of the information or product performance.

Alphabetical Case Study Listing

DfE Approach Case Study Listing

- **Materials Substitution**

- **Manufacturing/Production Changes**

- **Design for Disassembly for Reuse/Parts Replacement**

- **Reduced Transportation Impacts from Service Approach**

- **Waste Reduction**

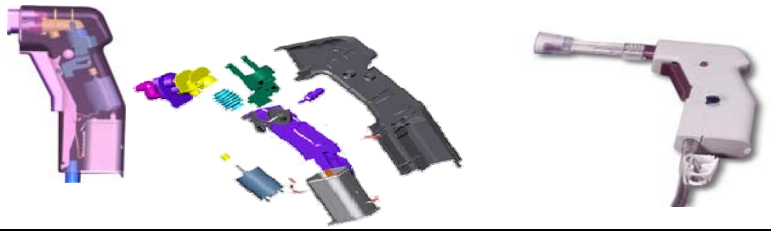
Case Study: AVIVA PVC-Free Intravenous Solution Containers

Product	**AVIVA PVC-Free Intravenous Solution Containers** 
DfE Concept	• Toxics avoidance • PVC and DEHP free
Product Description	Baxter Healthcare announced in April 2006 that it received approval from the U.S. Food and Drug Administration (FDA) for its new AVIVA premium line of intravenous solutions. While providing similar functionality and benefits of the company's VIAFLEX flexible container systems, AVIVA containers are made of non-PVC (non-Polyvinyl chloride) film, contain no latex, and offer a DEHP-free fluid pathway to patients. The new container line includes the most common and widely used intravenous (IV) solutions and is complemented by a broad offering of non-DEHP IV administration sets.
Environmental Attributes	• PVC- Free • Latex-Free • DEHP-Free • Serves the needs of sensitive populations, such as neonatal, pediatric and oncology patients
For Further Information	Baxter website - www.baxter.com

Case Study: Dade Behring Dimension RXL

Product	**Dade Behring Dimension RXL** 
DfE Concept	Waste reduction
Product Description	Engineered for maximum productivity, the Dimension® RxL™ System is a powerful and technologically advanced chemistry and immunoassay analyzer with over 60 available analytes for routine and special chemistries, thyroid function, and therapeutic drug monitoring. Some of the Dimension® RxL's capabilities include: • Sample integrity analysis -- HIL determination without reagent consumption or compromising throughput and productivity • Most methods plasma-approved for draw-spin-run • Automatically loads and removes Flex® Reagent Cartridges • No sample pretreatment for any method • No reagent preparation required by the operator • Auto-calibration of electrolytes (NA, K, CL) • One-touch early warning alerts for QC, STATs, sample, supplies, calibration • Outstanding calibration intervals • Load STATs at any time • Easy, flexible maintenance at your convenience • Simultaneous processing assures high throughput and fast TAT
Environmental Attributes	All of the Dimension® RxL's actual chemistry takes place in its cuvette. This is where the patient sample and the reagents mix and react. This instrument is a high throughput instrument so it utilizes hundreds of thousands of these disposable cuvettes during a working year. A normal approach to this challenge is injection molding individual cuvettes and then the user must develop a system that will sort, orient, place, and then dispose of the individual cuvettes. Dade Behring took a very unique approach in this area. They developed an on-board system that takes a roll of thin plastic film and then heats and blows the film into permanent metal cuvette wells. This allows for the absolute minimum amount of plastic to be used and for a relatively energy efficient manufacturing process. Normal injection-molded cuvettes require much more plastic to make them rigid enough to handle and the manufacturing process is more energy hungry. In terms of waste handling, the used cuvettes simply strip off the cuvette wells, still attached to the original roll of film, making disposal easy.
For Further Information	Design Continuum, Inc. - www.dcontinuum.com

Case Study: Davol Simpulse Lavage

Product Name	**Davol Simpulse Lavage** 
DfE Concept	Design for Disassembly for Reuse/Parts Replacement
Product Description	**Simpulse** provides irrigation, specifically pulsed lavage, during surgery as a primary application. The device is also used in other surgical applications and in wound management for pressure ulcers, diabetic ulcers, contaminated or infected wounds and burns. The device needed to be a powerful, highly variable irrigator, with high inherent safety, simple ergonomics, and low cost. Some predicate devices required off-board power which tethered the device to the power source and, in the case of gas-driven devices, created inherent safety risks. On-board power and pumping would free the device from the power source and surgeons preferred complete control over flow rate, ideally right in the handle. The variety of procedures in surgery and wound treatment required that the system be highly adaptable in terms of the nature of the irrigation flow and integration with suction. There was a huge market advantage if cost could be reduced to the point where the lavage could be applied in either a reusable or in a single-use manner. The basic design solution was to essentially invent a powerful pump that could be driven, on board within the handle, by a simple DC motor and four AA batteries. This patented solution met the performance specs, opening up clinical applications and market opportunities.
Environmental Attributes	The lavage was designed to allow the battery cartridge to be easily removed after surgery is complete. In most operations where a lavage is utilized, all operating materials are usually discarded and incinerated as medical waste. Making the lavage self-powered offered two important environmental advantages: • Added a reusability factor in the sense that the batteries could be used for other non-medical purposes; and • If the batteries were depleted during surgery, they could be easily removed and disposed of properly. The internal parts of the device were redesigned to simplify the manufacturing of the units and reduce the number of parts. Special attention was given to the design of the opening at the head of the unit so that it could accommodate a family of accessories.
For Further Information	Design Continuum, Inc. - www.dcontinuum.com

Case Study: Digital X-Ray (Several Manufacturers)

Product	**Digital X-Ray (Several Manufacturers)**
DfE Concept	Material conservation/waste reduction
Product Description	A traditional film-based x-ray system includes an x-ray generator, film, a phosphor screen, and a cassette. Digital systems work in a similar manner, but without the film. There are two types of digital systems, which are manufactured by various companies in Massachusetts. Computed radiography (CR) depends on the use of phosphor-based plates inside a cassette. The cassette is subsequently placed in a computer-radiography reader, where a laser scans and excites the image plate, digitizes the released image, and erases the imaging plate so it can be reused. Another method uses electronic arrays to generate electrical impulses or a microprocessor that converts light into electrical signals, which are then translated into an image.
Environmental Attributes	• Reduction in film and photoprocessing chemicals • Waste reduction • Operational efficiency • Enhanced worker safety
For Further Information	➢ Philips website - http://www.medical.philips.com/main/products/xray/products/radiography/digital/ ➢ GE Healthcare website - http://www.gehealthcare.com/usen/xr/radio/products/digital_xray/products/digdetector.html ➢ Fujifilm Medical Systems website - http://www.fujimed.com/products-services/imaging-systems/digital-xray/default.asp?location=1&area=10&id=0&subid=0

Case Study: DYONICS™ 25 Fluid Management System

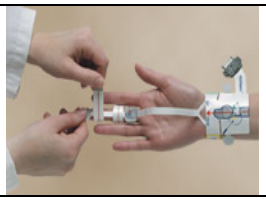
Product	**DYONICS™ 25 Fluid Management System** 
DfE Concept	• Reduction of material usage and waste through design • DEHP-free tubing • Latex free • Many RoHS compliant parts
Product Description	Launched by Smith & Nephew Endoscopy in 2005, the DYONICS 25 Fluid Management System is an easy-to-use, high flow pump for joint irrigation in all arthroscopic procedures. A new sterile tube set is inserted into the pump for use on each patient. A new style of tubing introduced with the DYONICS 25 System, "Day Tubing", reduces tubing material usage and medical waste by eliminating approximately 80% of the material used and disposed of for each patient. An additional benefit is that any partially used saline bags can also be carried over to the next patient instead of being disposed of, as sterility of the unused saline is assured. Material for the tubing has been selected to eliminate DEHP and Latex while maintaining the functional properties of the tubing. The parts count in all elements of the system has been minimized relative to its predecessor and, although medical devices are currently exempt from RoHS, the design of the DYONICS 25 System incorporated many RoHS compliant components.
Environmental Attributes	• DEHP-free • Latex free • Parts count reduction from predecessor device • Many RoHS compliant parts • Material usage and medical waste reduction
For Further Information	Smith & Nephew Endoscopy website - http://www.endo.smith-nephew.com/ (™ Trademark of Smith & Nephew. ©2006 Smith & Nephew, Inc. All rights reserved, (800) 343-5717)

Case Study: Medtronic Oxygenator

The following case study is taken from "Medtronic: A Case Study" published by the Minnesota Office of Environmental Assistance.

Product	**Medtronic Oxygenator** 
DfE Concept Illustrated	Reduced environmental impact during production.
Description	Medtronic successfully integrated DfE into the design of an oxygenator, a blood-processing product. There were two tools used by the design team (refer to Medtronic checklists in appendix) to evaluate environmental concerns. One of the tools, called the Environmental Product Design Evaluation Plan, consisted of yes/no questions, a series of easy-to-read flow charts and related documents. A second tool, the Materials Productivity Process Overview, was used to identify opportunities to improve the efficiency of materials use and the production operations. Both tools were used after the product conceptualization phase during the product design stage when the feasibility is studied and a prototype is developed.
Environmental Attributes	As a result of using the DfE approach, Medtronic recorded the following results: • A 75-85% reduction in chemical use and wastewater loading for a coating process, with an annual savings of $2.1 million. • A planned 30-35% reduction in material use and a 90% reduction in industrial solid waste generation from the manufacture of special cathodes for batteries used in cardiac rhythm management devices, with potential annual savings of over $200,000. • Analysis of alternative sterilization techniques and the identification of electronic beam sterilization as a viable alternative going forward.
For Further Information	➢ Full Medtronic case study - http://www.moea.state.mn.us/publications/dfe-medtronic.pdf ➢ Minnesota Office of Environmental Assistance Clearinghouse – (651) 215-0232 ➢ Medtronic website - www.medtronic.com

Case Study: NC-Stat System from Neurometrix

Product	**NC-Stat System from Neurometrix**  
DfE CONCEPT	Expanded services at the initial point of care reduces transportation impacts.
Product Description	The NC-Stat System is designed to perform standard non-invasive nerve conduction testing in the primary care physician's office. The system has three core components: (1) NC-Stat Biosensors – single use, nerve specific biosensors integrate transducers with a proprietary gel and temperature sensors in a configuration that ensures correct placement and accurate results; (2) NC-Stat Monitor – customizes and calibrates the test for each patient, analyzes the response waveforms collected from the biosensor, corrects response for skin surface temperature, displays nerve conduction response parameters in real-time on the LCD screen and stores data for convenient transmission to the onCall Information System; and (3) NC-Stat Docking Station – receives nerve conduction data and waveforms from the monitor and, at the physician's option, transmits that data to the onCall Information System at NEUROMetrix where the data is analyzed and a report generated for the physician within minutes.
Environmental Attributes	The wireless capabilities of this product/service results in: • Reduction in trips/transport for patients because NC-Stat allows primary care doctor to perform these neurological tests, allowing patients to avoid additional trips to specialists. (Note that specialists may still be available to review results)
For Further Information	Neurometrix website - http://www.neurometrix.com

Case Study: The Symphony® Breastpump By Medela

Product	**The Symphony® Breastpump By Medela** 
DfE Concept	• Material preference/avoidance • Design for Disassembly for Reuse/Parts Replacement
Product Description	These breastpumps use 2-phase expression®, the only research-based breastpump technology that mimics a baby's nursing rhythm by pumping in 2 distinct modes – designed for faster let-down and milk flow. The Symphony® Breastpump is a hospital grade pump available for home use on a rental basis. It features unique external software in the form of a microchip "smart card" that allows for the future development of customized program cards, so each mom can have a program designed to meet her needs. Medela also offers the Swing™ Breastpump, which is a new, single electric personal use product has been designed to be fully recyclable. A breast feeding company, Medela considers health, safety and environmental issues in the design of their products and services.
Environmental Attributes	• DEHP-Free. • Removal of Bis-phenyl A from any polycarbamate in contact with breast milk. • Replacement of polycarbamate with polypropylene for some components because polypropylene can withstand autoclaving which allows the reuse, in hospitals, of breast milk storage containers. • Leasing/refurbishment program to extend product life. • Goal of company is to be RoHS compliant in 2007, although company products are not currently covered by RoHS. • Swing™ Breastpump was designed for easy disassembly and recycling of all components, as well as RoHS compliance. • Designed for minimal energy usage. • Evaluating consumer-based recycling program for personal use products.
For Further Information	Medela website - http://www.medela.com/

Case Study: VISIV™ Flexible Intravenous Container From Hospira

Product	**VISIV™ Flexible Intravenous Container From Hospira** 
DfE Concept	• Waste reduction • Toxics avoidance
Product Description	Hospira has launched the VISIV flexible intravenous container made from a polyolefin/polyester laminate. The VSIV container's built-in patient and caregiver-safety features help to increase patient well-being and enable enhanced and more efficient medication delivery including: • No overwrap helps caregivers provide intravenous therapy to patients more rapidly, by eliminating the steps of removing and discarding the overwrap. • Ergonomic pull-rings covering the sterile ports help reduce risk of contamination and the potential for healthcare acquired infections. • The container's sterile ports provide another potential benefit to the patient, as medication can be immediately added to the container. • The tamper-evident port system provides visual evidence to caregivers that a medication has not been added to the VISIV container.
Environmental Attributes	• As a result of no overwrap, the container results in approximately 40 to 70% less waste than other flexible I.V. containers. This is important since, on average, U.S. hospitals generate 6,600 tons of waste each day, of which nearly 800 tons are plastic products. • Made from PVC- and DEHP-free materials that provide thermal stability, moisture-barrier properties and inertness required for I.V. medications. • Minimized risk of needle stick injuries.
For Further Information	Hospira website - http://one2one.hospira.com/default.aspx

Appendix A

Office of Technical Assistance and Technology Compliance Assistance Services

The Office of Technical Assistance and Technology (OTA) in the Commonwealth's Executive Office of Environmental Affairs provides a range of non-regulatory assistance services to all Massachusetts toxics users at no cost, and on a confidential basis. Since its creation in 1990, OTA has successfully assisted Massachusetts businesses in various industry sectors with reducing the use of millions of pounds of toxic chemicals while saving millions of dollars. OTA provides a variety of services to help businesses cut costs, improve chemical use efficiency, and reduce environmental impact in Massachusetts.

About OTA Staff

OTA scientists and engineers are highly trained and knowledgeable of most manufacturing operations – where many began their careers. Each staff person is dedicated to maintaining OTA's high standard of technical service by keeping current on the critical environmental issues and technological advances in their industry sector. They understand both the technical issues of implementing toxics use reduction approaches and the environmental regulations that apply to a facility's operations. Click here for information on OTA's staff.

Compliance Assistance Programs and Services

At no charge to the facility, OTA staff can provide toxics users in the Commonwealth assistance in reducing chemical use and waste, maximizing process efficiency, improving regulatory compliance for the purpose of improving productivity, reducing costs and minimizing exposure to liability. Click here for more information on OTA's on-site services.

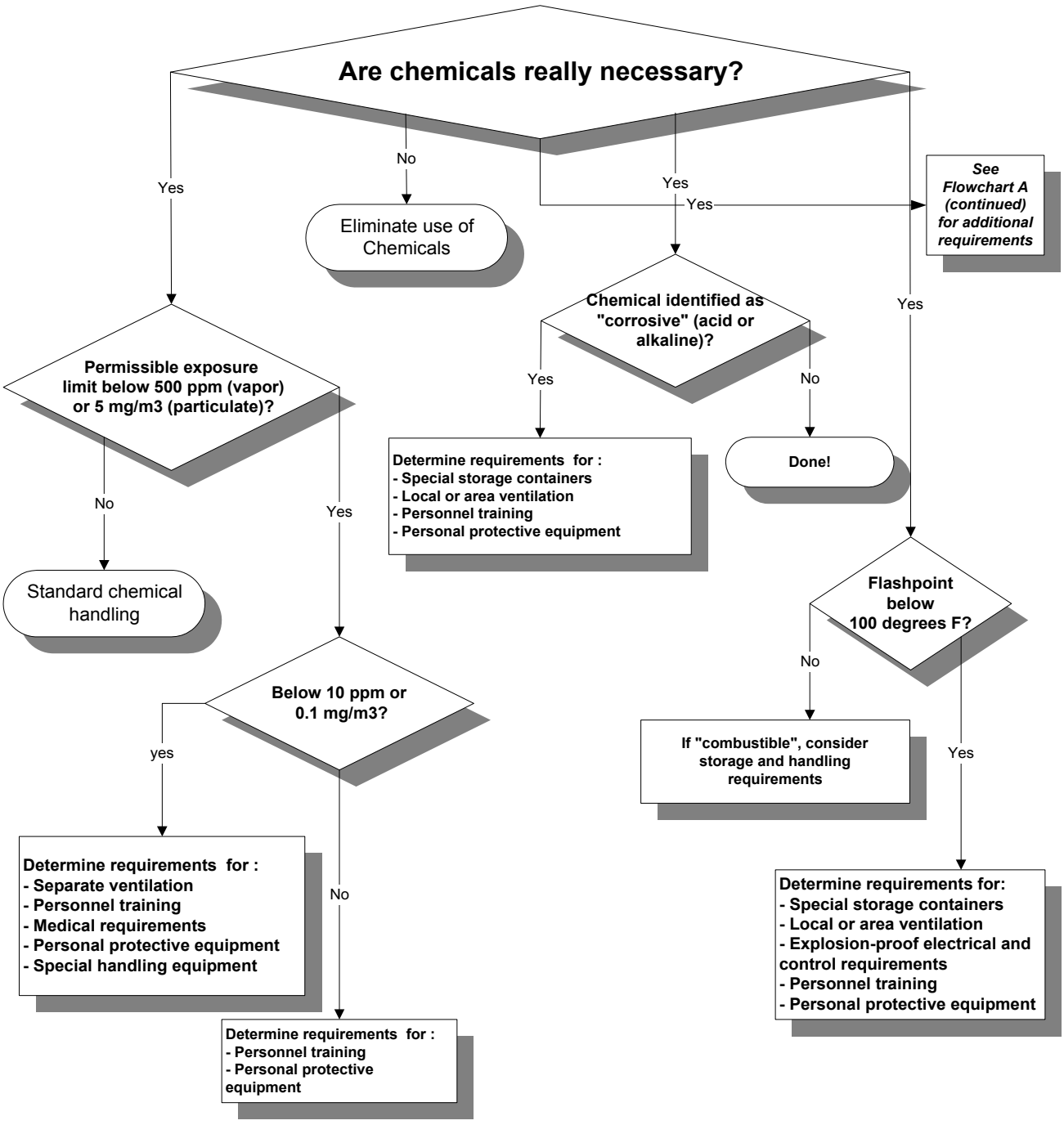
OTA's Right from the Start Program specifically targets companies that are building a new facility or addition to an existing facility to design pollution out of the new operations, preferably before construction or modification begins, and/or to assist with environmental permit technical issues.

OTA offers various publications, including written case studies, fact sheets, an electronic newsletter, and technical guidance documents and reports to assist toxics users find solutions to vexing environmental challenges. The Office has also developed a number of software applications to help facilities monitor operations, improve efficiency, reduce waste and comply with particular reporting requirements.

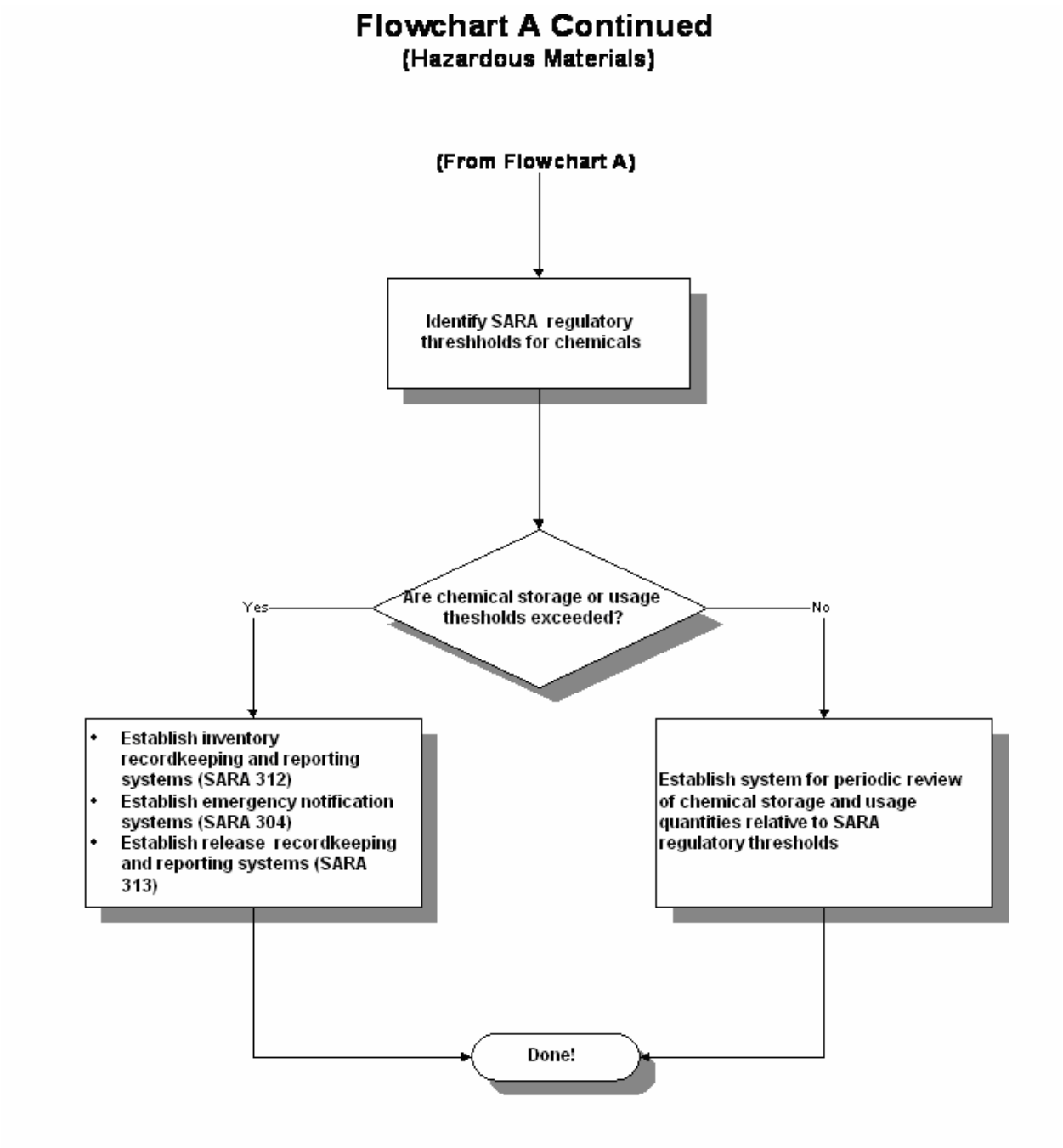
Appendix B

Appendix B-1
Sample DfE Checklist

Flowchart A
(Hazardous Materials)

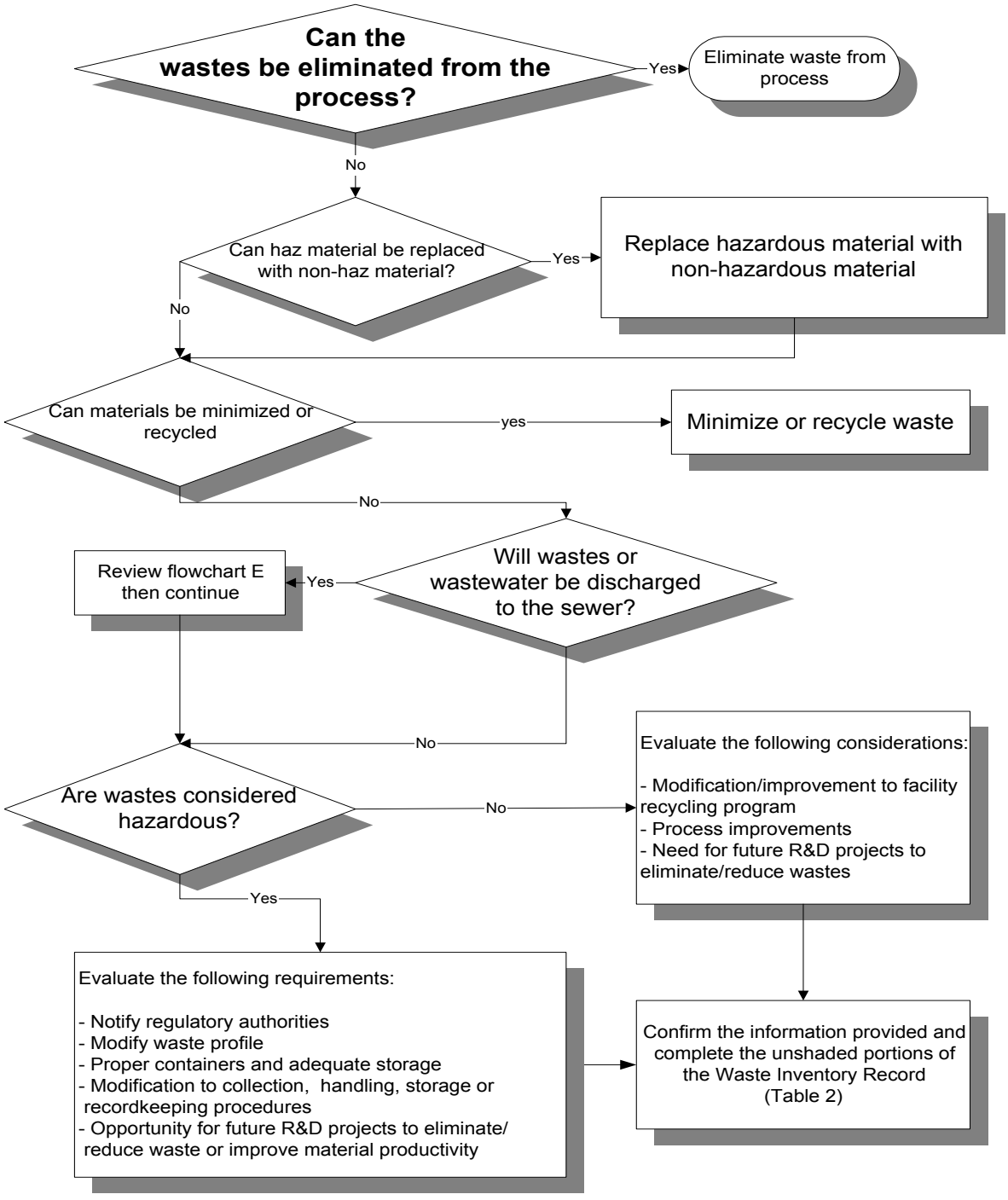


Confirm information and complete unshaded portion of Table 1 of Appendix B-2.

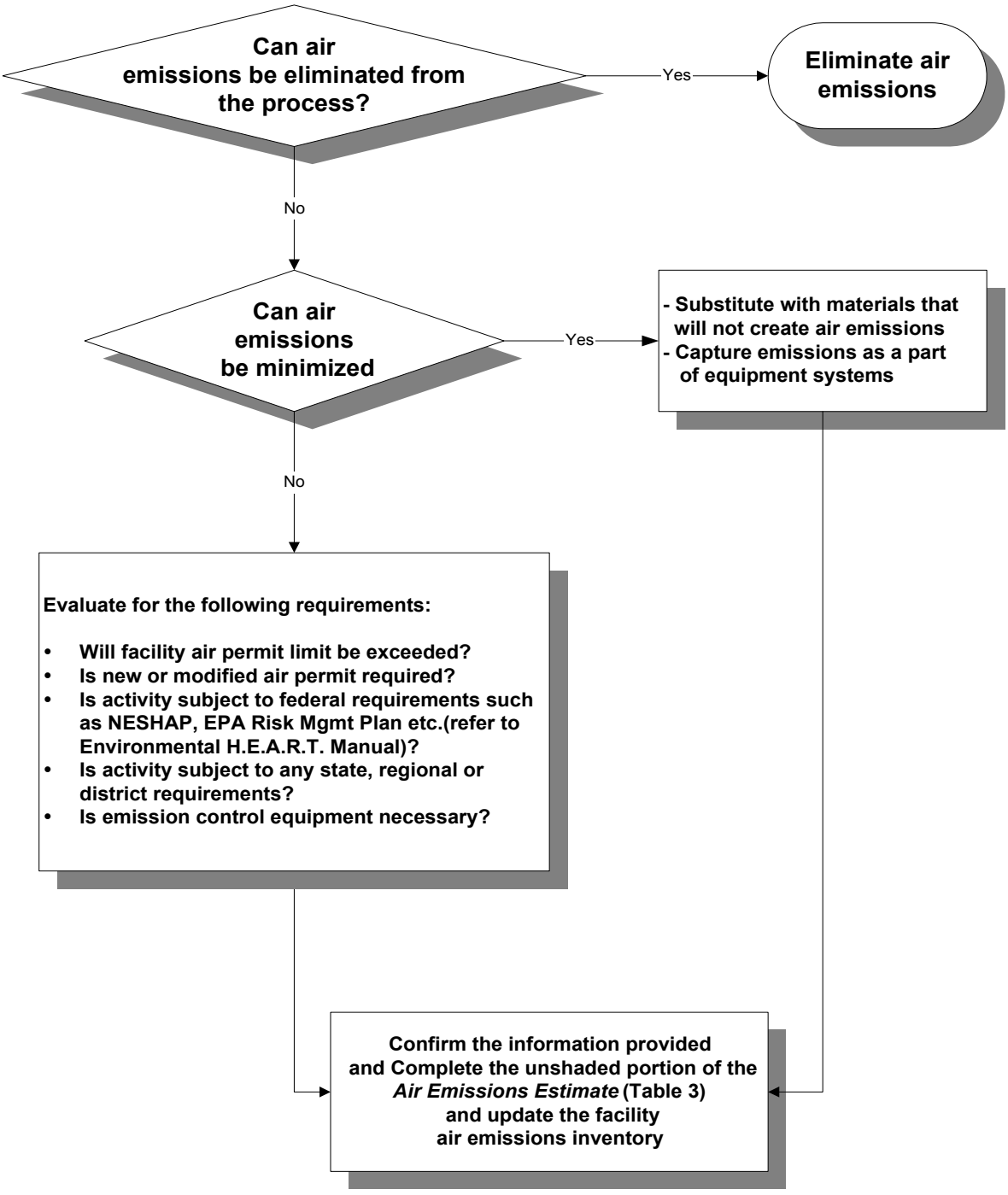


Confirm information and complete unshaded portion of Table 1.

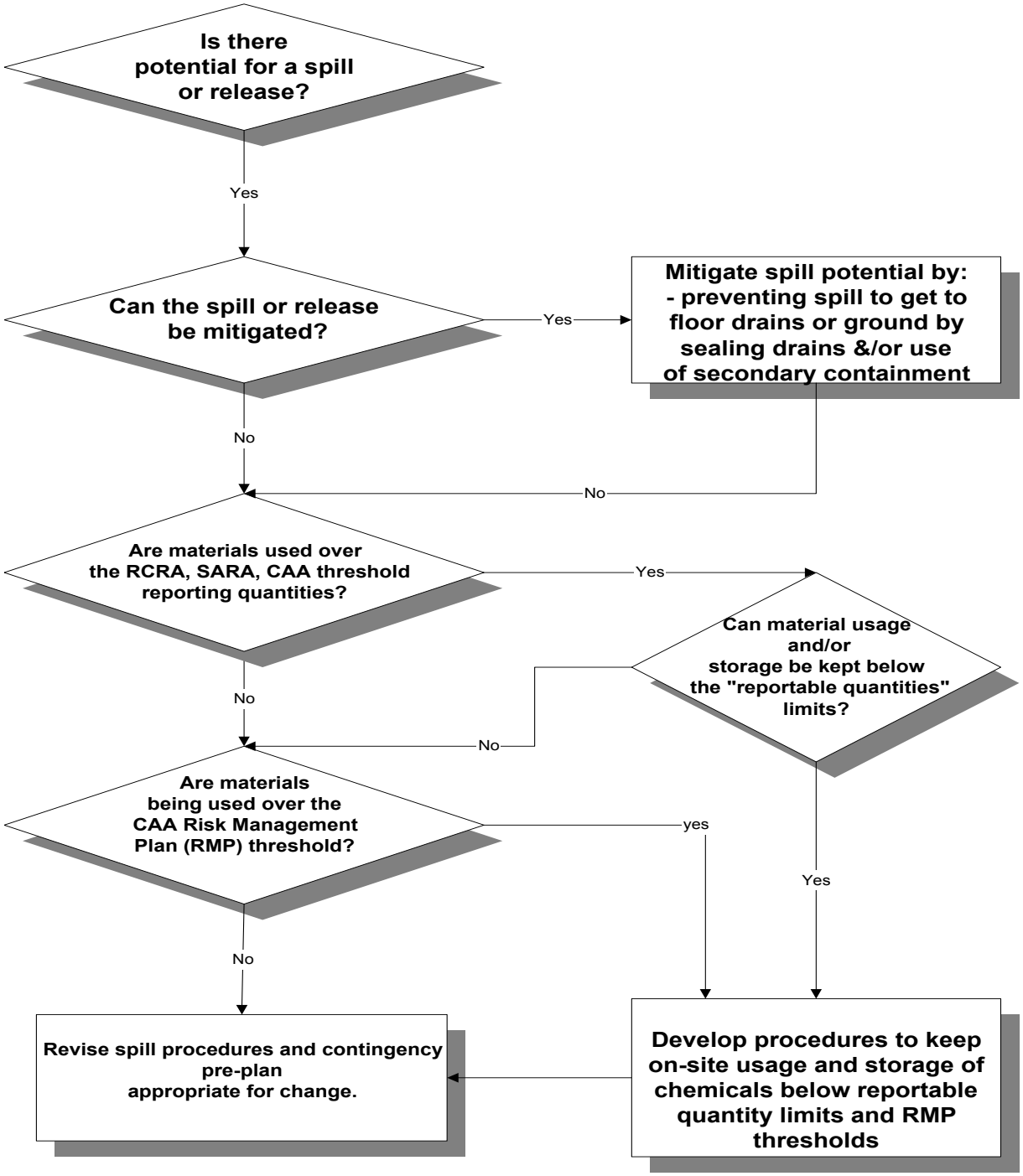
Flowchart B
(wastes)



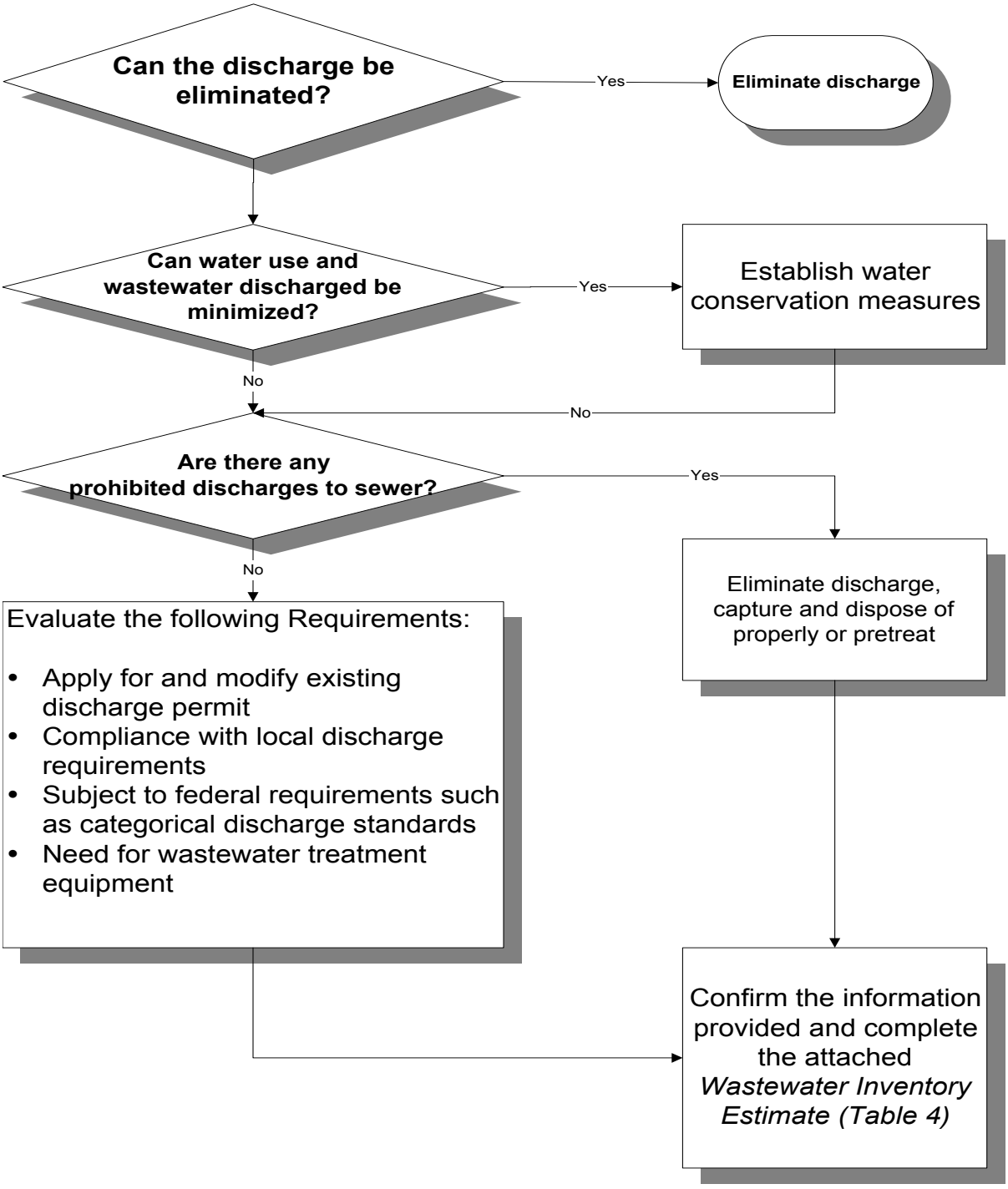
Flowchart C
(air emissions)



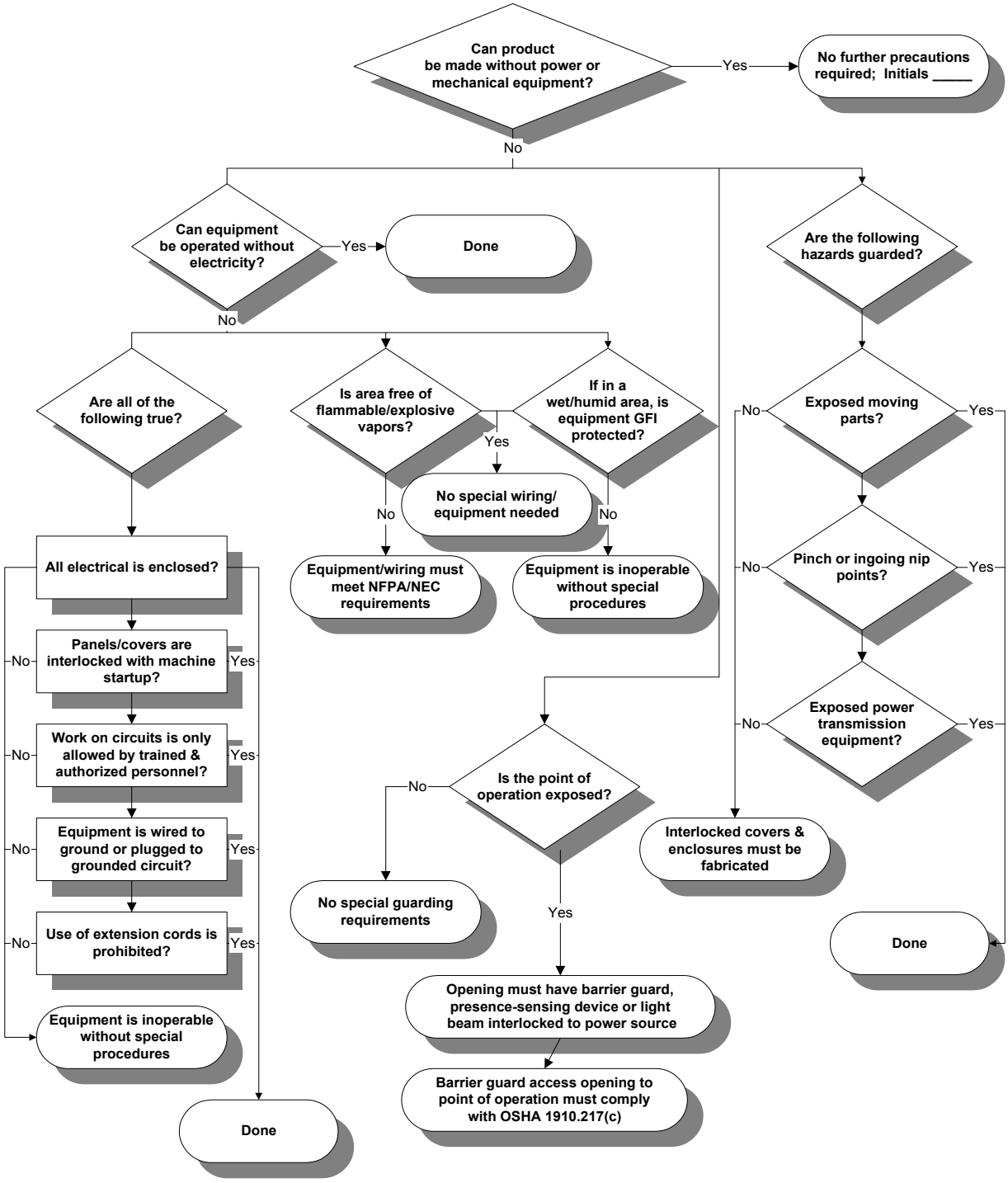
Flowchart D
(spill or release)



Flowchart E
(water / wastewater)

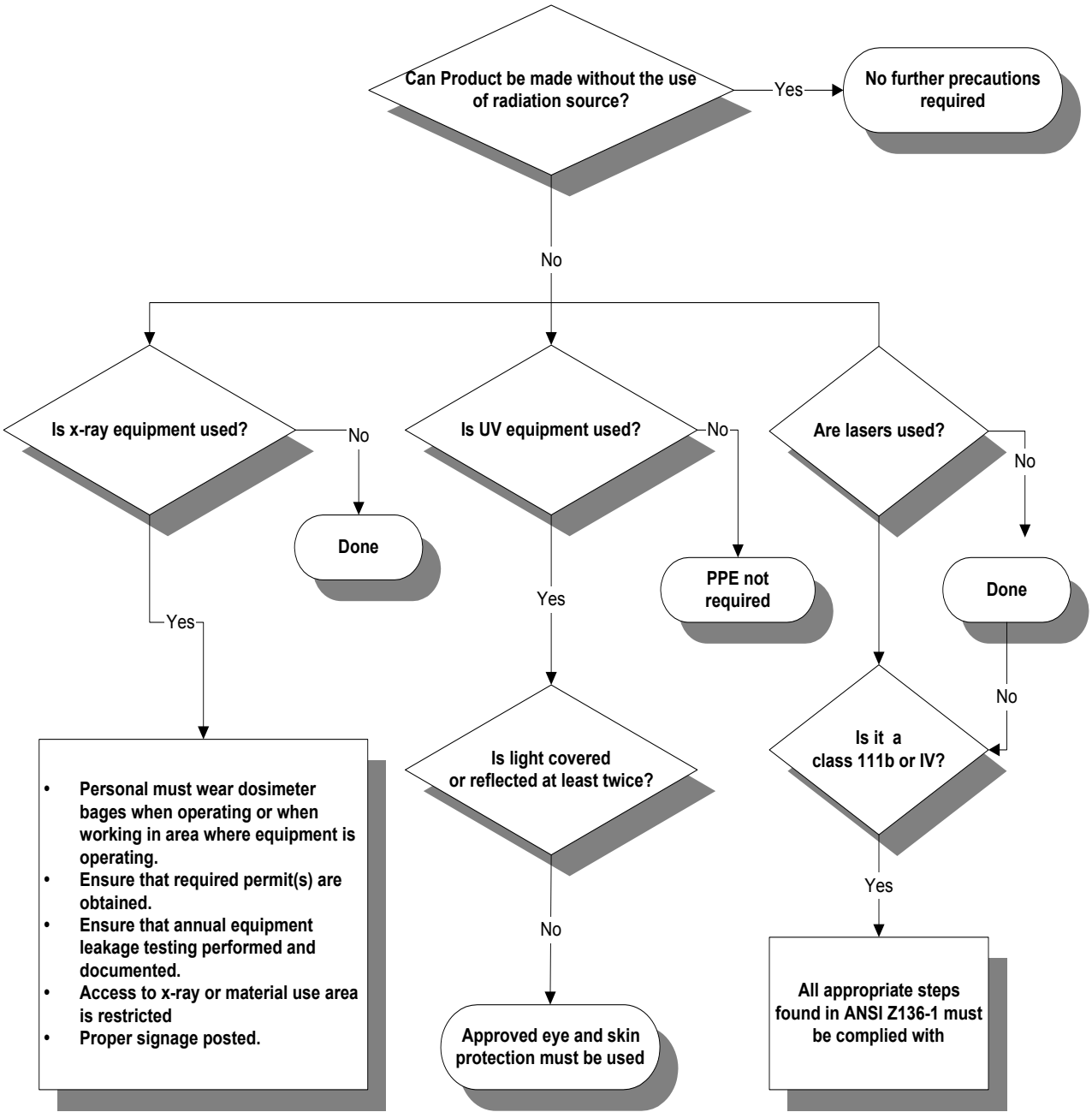


Flowchart F
(Equipment Use / Energy Hazards)



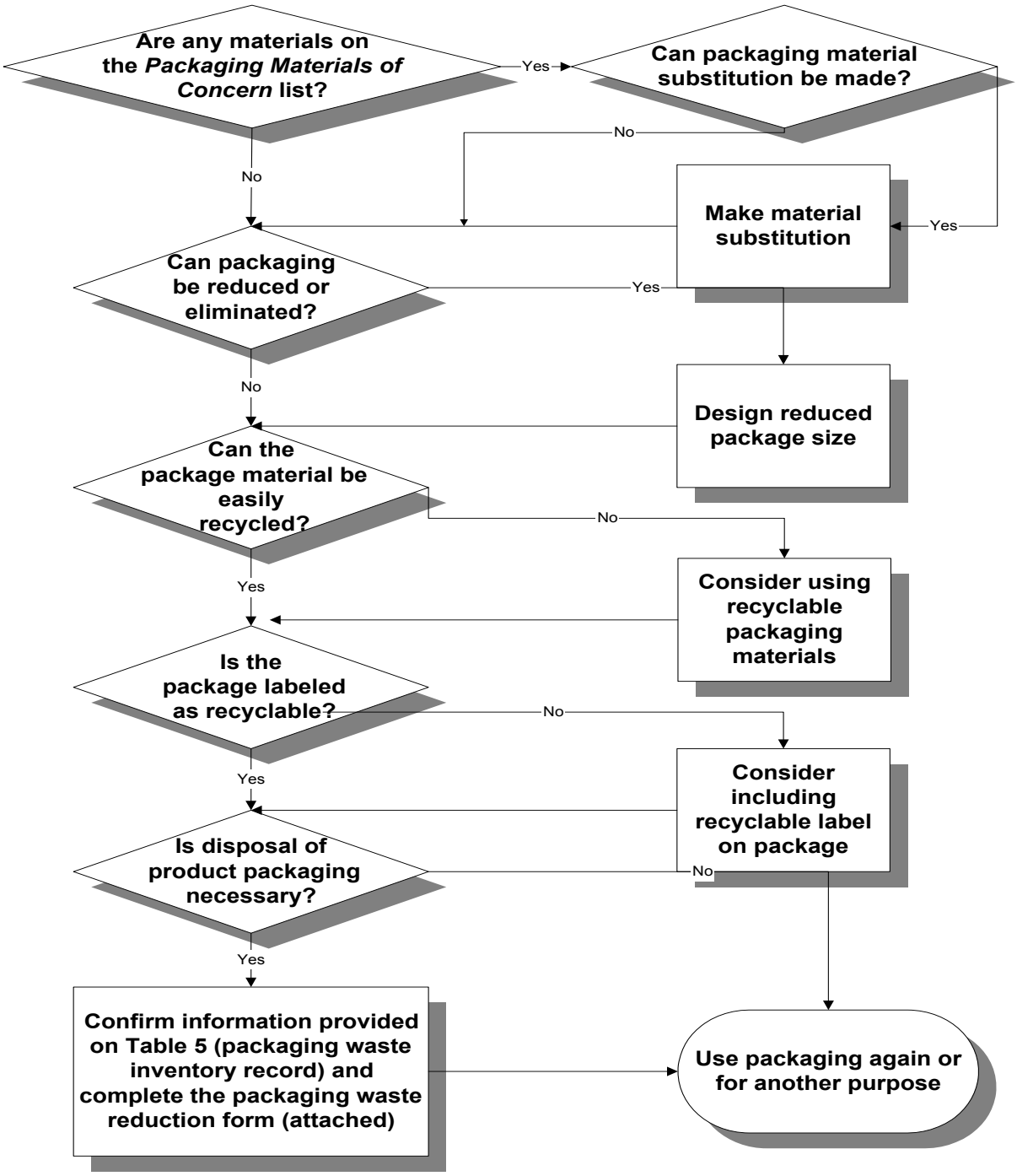
Confirm information and complete unshaded portion of Table 5.

Flowchart G
(Radiation Exposure Hazards)



Confirm information and complete unshaded portion of Table 5.

Flowchart H
(packaging)



Appendix B-2

Appendix B-2
EHS Product Design Evaluation Plan

It is the responsibility of the project or program manager to ensure that this EHS evaluation is conducted during the product design process. Please answer each question yes (Y) or no (N). If yes, complete the referenced table. See definitions for questions on a term.

Section I: Materials

1.0 Will hazardous materials be used to produce this product?	Y / N	If yes, answer 1.1 - 1.4 (If no, go to section II)
1.1 Will employees be potentially exposed to any chemicals?	Y / N	If yes, complete shaded portions in Table 1 (if no, go to 1.2)
1.2 Will any wastes be generated from manufacture of this product (for example: adhesive solid waste (scrap), biomedical, etc.)?	Y / N	If yes, complete shaded portions in Table 2 (if no, go to 1.3)
1.3 Will there be any air emissions from manufacture of this product (for example: solvents, paints, epoxies, particulates, etc.)?	Y / N	If yes, complete Table 3 shaded portions. (if no, go to 1.4)
1.4 Is there potential for spill or release from manufacture of this product to sewer, air or ground? (see flowchart D for guidance)	Y / N	Go to Section II

Section II: Water

2.0 Will the manufacture of this product require the discharge of water?	Y / N	If yes, complete Table 4 shaded portions. (If no, see Section III)

Section III: Equipment

3.0 Will this product require the purchase of new equipment or modification of existing equipment?	Y / N	If yes, go to Table 5 (If no, go to Section IV)

SECTION IV: PRODUCT PACKAGING

4.0 Is sales or transport packaging required for the product?	Y / N	If yes, complete Table 6 (If no, go to Section V)

Section V: Product Disposition (End-of-Life)

5.0 Will the product require disposal by the end-user?	Y / N	If yes, complete shaded area of Table 7

Section VI: Facility Modification

6.0 Will manufacture of this product involve a facility modification (structural change, venting, electrical, plumbing, etc.),	Y / N	If yes, complete Table 8

The signature below certifies that the above EHS design criteria have been considered and incorporated as applicable. This checklist and attachments are to be maintained as documentation of this evaluation.

(Program/Project Manager Name)	(Signature)	(Date)

Table 1. Listing of Hazardous Materials and EHS Requirements

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Hazardous Materials Name (Attach Material Safety Data Sheet for each material	Estimated Quantity/year (lbs or gal)	Estimated Quantity stored on-site at any time	Requirement*	Responsibility Department/ Name	Date Completed

* These requirements include training, personal protective equipment, storage areas and containers, ventilation, IH monitoring, MSDS, plans, etc. Refer to flow chart A for guidance.

Table 2. Waste Inventory Estimate

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Waste Description	Estimated Quantity/Month (lbs or gal)	Requirement*	Responsibility Department/Name	Date Completed

* These requirements include providing adequate storage areas and containers, generating or modifying wastestream profiles, obtaining or modifying permits or licenses (e.g., POTW, air, etc.), ensuring proper regulatory disclosure, establishing disposal options, etc. Refer to Flowchart B for guidance.

Table 3. Air Emissions Estimate

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Chemical Name	Emission Estimate (lbs/month)	Requirement*	Responsibility Department/Name	Date

* These requirements include providing adequate local or area exhaust ventilation, emission control equipment, obtaining or modifying permits registrations or licenses, ensuring proper regulatory disclosure, etc. Refer to Flowchart C for guidance.

Table 4. Wastewater Inventory Estimate

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Wastewater Discharge Description (Include chemical/material contaminants)	Est. Volume (gal/month)	Requirements*	Responsibility Department/Name	Date

· These requirements include prohibited discharges are prevented; compliance with discharge limits and permit conditions. Also, any opportunity to the Reduction of water or wastewater should be pursued. Refer to Flowchart E for guidance.

Table 5. Equipment Record

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Description of Equipment	Energy Components (electrical, mechanical, laser, other*	Pressurized gases * (type i.e. nitrogen, oxygen, etc.)	Radiation Use (i.e. X-Ray, Ultraviolet isotopes, other)**	Ergonomics body area of repetitive motion

* Go to Flowchart F for guidance on Energy Hazards.
** Go to Flowchart G for radiation Exposure Hazards.

Table 6. Packaging Waste Inventory Record

Name: _____ Date: _____
Product/Manufacturing Process: _____ Business Unit: _____

Packaging Material	Weight per package	# Packages per Year	Weight of Package Waste per Year	Proposed Recycle/ Disposal Method

Are there any packaging materials or inks/dyes on the list below? Yes/No
If yes, be sure to identify above.
Packaging Materials of Concern:

1) halogenated polymers such as:
- **polyvinyl chloride (PVC)**
- **polyfluoroethanes**
- **polyvinylidane chloride**

2) plastic compounds or inks/dyes containing the following metals:
- **arsenic**
- **mercury**
- **chromium**
- **lead**
- **tin**
- **silver**
- **cadmium**
- **copper**

3) plastic components containing chlorinated or brominated additives >1 mg/kg such as:
- **polychlorinated terphenyls**
- **chlorinated paraffins**

4) the following phthalates >1 mg/kg:
- **dimethyl phthalate**
- **diethylhexyl phthalate**
- **diethyl phthalate**
- **di-n-butyl phthalate**

5) products containing lead, cadmium or mercury >1 mg/kg

6) chlorine or hypochlorite bleached paper

Refer to Flowchart H to identify opportunities for improved package design.

Table 7. Product Disposal (End of Life) Record

Section A:	
Business: _____	**Disposal Method:** _____
Product/Process: _____	**Date:** _____

Are any of the materials to avoid listed below in this product? Yes/No. If yes, complete Section B.
Materials to avoid:

- carcinogens
- cadmium
- ethylene oxide
- lithium
- mercury
- arsenic
- silver
- tin
- halogenated polymers
- lead
- methylene chloride
- CFCs (Freon)
- HCFCs

Section B: **Product Components**	(1) **(2)** Material of Concern	(3) Requirement/Opportunity *	(4) Verification **Responsibility Department/Name**	Date

* Refer to Flowchart I to help identify requirements and opportunities for improvement.

Appendix B-2
EHS PRODUCT DESIGN EVALUATION FORM

Table 8. Environmental, Health and Safety (EHS) Evaluation for Facility Design Products

The intent of this document is to be used as a screening tool to identify any significant EH&S issues during the facility design process which includes new facility construction or existing facility remodeling. It is the responsibility of the facility project manager to ensure that the following EHS evaluation is conducted during the facility design process and retained in the facility project file. The scope of this evaluation includes future operations within the construction or remodeling area and any contractor activities. The EHS Coordinator will investigate those questions answered "yes" (Y)

Facility Location: _____ **Date:** _____

Description of Facility Modification: _____

_____

_____

_____

Contact Person: _____

1.	Will chemicals or pressurized gases be used or stored in the new or remodeled facility?	Y/N
2.	Will employees be exposed to any chemicals or biologically contaminated products?	Y/N
3.	Will solid, hazardous or biohazard wastes be generated or stored in or near the facility?	Y/N
4.	Will there be any air emissions?	Y/N
5.	Does the facility modification involve the discharge of wastewater?	Y/N
6.	Are there any new potential hazards to employees from mechanical, electrical or radiation energy sources? (presses, lasers, x-ray, welders, etc.)	Y/N
7.	Does the facility project involve the removal or handling of asbestos-containing materials or PCB-containing materials or articles?	Y/N
8.	Does the project involve moving people and/or workstations (e.g., tables, cubicles, desks) or installing new workstations (ergonomics)?	Y/N
9.	Are fume exhaust hoods or process ventilation ducting being moved or installed?	Y/N
10.	Will the planned modifications require welding or cutting tasks to be completed?	Y/N
11.	Will construction require interruption to the facility's fire sprinkler service?	Y/N