SUMMARY OF DISCUSSIONS, FINDINGS AND NEXT STEPS

from the June 24, 2004 Focus Group Meeting with Massachusetts Medical Device Manufacturers

FINAL REPORT

August 2004

Executive Office of Environmental Affairs

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Executive Summary

The medical device industry is important to the future growth and economic development of the Commonwealth. The industry's growth offers a unique opportunity for good wages and professional growth for employees, as well as for providing revenue to communities and the state. To support it's continued growth and to reduce potential environmental barriers and liabilities impeding the growth of the sector, the Massachusetts Office of Technical Assistance for Toxics Use Reduction (OTA) held a focus group meeting with the manufacturers of the following three types of medical devices in Massachusetts – surgical and medical instruments; electromedical and electrotherapeutic apparatuses; and surgical appliances and supplies. The meeting was held June 24, 2004 at Nypro's corporate facilities in Clinton, Massachusetts. It is important to note that this meeting was a rare opportunity for environmental, health and safety (EH&S) representatives in the medical device sector to meet each other, and collectively share their insight, experiences and knowledge. The medical device EH&S representatives at the meeting suggested that they do not generally interact through a professional or trade association, and expressed interest in maintaining this type of dialog in the future.

Topics for discussion were identified in advance of the meeting based on research and preliminary discussions with the participants. These topics included: (1) environmental regulatory compliance issues; (2) implementation of toxics use reduction and Design for the Environment (DfE) principles; (3) reuse and recycling of materials; (4) waste reduction through operational efficiency; (5) supply chain management; and (6) key linkages with other organizations and industries to enhance competitiveness. These issues were discussed at length and a summary of these discussions serves as the foundation for this report, beginning on page 6. Based on these discussions, a number of preliminary action items, or next steps, were identified. A full description of potential next steps is found on page 15.

Short term steps for OTA and the Executive Office of Environmental Affairs (EOEA) include:

- Drafting and sending an appreciation letter from the Secretary of Environmental Affairs to the CEOs of the companies who participated in the Focus Group meeting;
- Communicating environmental concerns identified at the Focus Group Meeting to program managers at the Massachusetts Department of Environmental Protection and the Department of Public Safety; and
- Following up with certain medical device manufacturer participants who expressed an interest in an OTA site visit.

Long term steps for OTA and EOEA include:

- Evaluating the Food and Drug Administration (FDA) policy and history vis-a-vis approval of process changes at registered medical device manufacturing facilities, and working with relevant stakeholders to promote, through education or policy change, chemical substitution, process changes, water conservation and waste recycling without triggering the approval of change process; and
- Developing and implementing a strategic plan to provide technical and regulatory assistance to this important sector. The plan may include elements such as preparing

regulatory guidance for startups and case studies; providing on-site technical assistance; and organizing and conducting workshops for R&D staff and senior executives.

OTA will be developing the workplan in the coming months for the implementation of next steps in FY05. Comments and suggestions with respect to this report and potential next steps are welcome. Please send them to the Project Leader, John Raschko, at john.raschko@state.ma.us

Background

OTA is a non-regulatory service provider to all Massachusetts toxics users and is a part of the Commonwealth's Executive Office of Environmental Affairs (EOEA). In addition to its on-site technical and compliance assistance services, OTA brings a technical and industry perspective to assist EOEA's policy initiatives. OTA is currently supporting Secretary Ellen Roy Herzfelder's Lean and Green streamlining efforts. The Lean and Green agenda looks to make the regulatory process more predictable for the private sector while maintaining or improving the level of protection of the environment, promote local and innovative environmental technologies and companies, and improve internal government operations - making them more efficient and less costly.

Purpose

In the context of the Lean and Green agenda, the goal of the focus group was to initiate a discussion of key environmental issues faced by medical device manufacturers for the purpose of assisting OTA in:

(a) understanding the environmental challenges and opportunities associated with the design, manufacture and sale of medical device products;

(b) brainstorming policy and regulatory streamlining opportunities (e.g., discuss opportunities to make regulatory compliance more certain and/or flexible); and

(c) identifying the types of services that OTA can provide to this sector to enhance the competitiveness of Massachusetts medical device companies in global markets while reducing the use of toxic substances (e.g., regulatory compliance assistance and technical support to address identified environmental challenges).

Methodology

A consultant, Nexus Environmental Partners, was engaged to assist OTA in identifying potential participants for the Focus Group meeting, researching relevant environmental issues and facilitating the meeting. OTA made every attempt to include broad representation at the meeting, including large and small companies, geographically diverse companies and representatives from different functions within the organization (e.g., environment, health and safety, facilities, manufacturing, finance, etc). Appendix 1 includes meeting participant information and Appendix 2 includes a listing of the medical device manufacturers and associated firms contacted in advance of the Focus Group meeting.

OTA also researched literature, conducted interviews with company and association representatives, and evaluated relevant U.S. Environmental Protection Agency (EPA) and Massachusetts databases (e.g., Toxic Use Reduction Act filers, hazardous waste generator lists, air permit records) for information regarding the medical device sector. A general characterization of the medical device sector and, more specifically, manufacturers of surgical and medical instruments, electromedical and electrotherapeutic apparatus and surgical appliances and supplies can be found in Appendix 3. Appendix 4 includes reference materials and documents used to prepare for the Focus Group meeting and to write this Final Report.

Focus Group Agenda

Based on our research and preliminary understanding of medical device manufacturing operations and activities, regulatory compliance challenges and competitive enhancement opportunities issues, we put together the focus group agenda and the topics for discussion. The topics for discussion were categorized as follows:

1. Regulatory Compliance Issues
2. Efforts to Implement Toxics Reduction and Design for the Environment (DfE)
3. Reuse/Recycling Initiatives – Within the Plant and Third-Party Collection
4. Efforts to Improve Operational Production Efficiency
5. Supply Chain Management – Suppliers and Customers – to Achieve Environmental Benefits
6. Key Organizational Linkages to Enhance Competitiveness

The topics were presented as questions, and relevant issues were identified based on our initial research. The complete listing of questions with respect to the environmental issues facing the medical device manufacturing sector is included as Appendix 5.

We were particularly interested in understanding the "drivers" that have affected – or will affect – environmental performance. For example, it is clear that the U.S. Food and Drug Administration (FDA) approval process is the most significant regulatory constraint facing the industry. The Quality System (QS) regulations are, perhaps, most relevant to the environmental, health and safety topics covered by the Focus Group meeting. These regulations, promulgated under section 520 of the Food, Drug and Cosmetic Act (FD&A) in 221 CFR 820, require manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of the finished medical devices intended for commercial distribution in the United States. Opportunities exist to consider environmental (as well as health and safety) issues during the preparation of design reviews and design validations, which take into account an array of customer and user needs, and integrate efforts to minimize impacts and manage environmental issues into the FDA regulatory process.

The FDA requirements are not, however, the only regulatory driver. International, federal, and state environmental requirements may be an important regulatory driver of decisions affecting the design and manufacture of components, devices, and packaging. For example, there has been a growing movement, particularly in Europe, to restrict the use of certain substances or materials and to control the end-of-life disposal of electrical equipment and electronics. While medical

devices have generally been exempt to date, restrictions on the use of materials, such as dyes and metals in packaging, have been enacted and the future of existing exemptions is unclear.

Some medical device manufacturers, such as Baxter Healthcare, have responded to these existing or potential restrictions on the use of component materials and end-of-life management dictates and looked for opportunities to strengthen the bottom line and demonstrate environmental leadership. We, therefore, sought information about the environmental leaders in the industry, and the range of marketplace drivers that enhanced the "environmental" value proposition.

The final agenda for the meeting is included as Appendix 6.

Focus Group Meeting

The Focus Group meeting was held June 24, 2004 at Nypro's corporate headquarters and manufacturing facility in Clinton, Massachusetts, and commenced at 8:30 am. Based on participant evaluations, the meeting was very successful.

Welcome and Introductions

Participants were welcomed by John Raschko, Ph.D. from the Office of Technical Assistance, the project team leader for the medical device initiative.

Stephen Pritchard, Chief Operating Officer, EOEA, also welcomed the participants and expressed the support of the Romney Administration, and Secretary Ellen Roy Herzfelder in particular, in sustaining the growth of the medical device sector through sensible, protective and streamlined environmental regulations. He expressed great interest in hearing more about specific environmental regulatory challenges for the purpose of identifying opportunities for EOEA to assist medical device manufacturers achieve comparable or enhanced environmental protection, with less process and bureaucracy.

Paul Richard, Director of OTA, provided an overview of the organization, which is a non-regulatory service provider to industry and part of EOEA. OTA was formed in 1990 by the Toxic Use Reduction Act (TURA) and has provided on-site services to over 1,100 manufacturing facilities reducing toxic chemical use by more than 10%. Moreover, 185 companies subject to TURA reporting with whom OTA has worked have cut chemical use to below reporting thresholds, resulting in savings of more than $22 million. In addition to its on site services, OTA brings technical and industry perspective to assist EOEA's policy initiatives such as Secretary Ellen Roy Herzfelder's Lean and Green Regulatory Streamlining efforts. Paul reviewed the six topics to be addressed during the facilitated discussion and encouraged the medical device sector representatives to "set their own public agenda" by articulating their needs and working with the state environmental agencies to achieve environmental protection in the most efficient and cost-effective manner.

Participants were then asked to introduce themselves, describe their roles and responsibilities within their organizations and identify key environmental issues. Common concerns voiced by the participants included, among other topics, (a) FDA issues associated with production changes; (b) challenges associated with incorporating "Design for the Environment" principles

early in the design and technology transfer process; (c) European "green" drivers (e.g., restrictions, prohibitions) versus perceived U.S. inertia; (d) green procurement as it pertains to Europe and Asia; and (e) interest in anticipating and proactively responding to potential environmental roadblocks.

Industry Success Stories

After the initial welcome and introductions, representatives from Genzyme Biosurgery and DePuy Orthopaedics presented case studies regarding successful, cost-effective initiatives to prevent pollution. These presentations were designed to (a) bolster the fact that environmental protection and cost-savings can work hand-in-hand and (b) acknowledge the efforts of some of the Commonwealth's leading companies.

Joan Boegel, Associate Director of Environmental Affairs for Genzyme, described the company's efforts to better manage alcohol waste. Alcohol waste is generated as a by-product of biopolymer purification at its Framingham facility. The mixture waste is considered a characteristic hazardous waste due to its ignitability. From 1997 – 2001, this waste stream was sewered to a process wastewater pretreatment system, in accordance with Massachusetts Water Resources Authority (MWRA) compliance limitations. Beginning in 2001, a new management strategy was necessary because of planned production increase (and greater alcohol waste volume) and MWRA concerns about Biochemical Oxygen Demand (BOD) in discharges to the Framingham Extension Sewer. The company explored on-site recycling, but it was rejected because of a number of issues, including capital costs and the potential need to revalidate the process for FDA approval. On-site incineration was deemed impractical because of environmental permitting obstacles. Off-site recycling, while initially expensive, provided some clear benefits: it was available through the use of a Class A Recycling permit; material conservation was consistent with the firm's environmental principles; the waste could be managed as a "regulated recyclable material" and was therefore exempt from hazardous waste manifesting and fees; and the recycled material would not count toward the generation volumes. In deciding to recycle the material off-site, the following success was achieved: (a) high BOD alcohol waste discharge to MWRA was eliminated; (b) three distillation facilities were identified and qualified (none in the northeast); (c) price has decreased more than 80% as a result of competitive bidding; and (d) the facility's hazardous waste generation rate has dropped below the Large Quantity Generator (LQG) threshold.

Jean Palmateer, Environmental Affairs Director at DePuy Orthopaedics, described two successful examples of production process changes that led to improvements in environmental performance and financial savings. In the first example, she described a process change at the New Bedford manufacturing facility from a traditional metal plating/heat treatment operation to the use of a nitrogen oven (i.e., inert atmosphere) to provide heat treatment for stainless steel. The nitrogen system allowed the company to avoid the use of hazardous chemicals, minimize the generation of hazardous waste, and conserve energy as well as minimize oxidation and distortion of the finished product. In the second example, she described DePuy's former use of "traditional" plating/coating operations of stainless steel that used more than 8 million gallons of fresh water per year at its molding/casting facility in Raynham. The plant was able to reduce water usage by 30% by designing and installing an automated, counter-current rinsing and rinse

cascading system. Additionally, conductivity sensors were installed to better determine the need for additional rinse water, as necessary.

Facilitated Discussion

The agenda allowed for more than two hours of facilitated discussion and a lively discussion ensued. Participants were arguably most engaged and interactive in the discussion regarding the challenges associated with implementing Design for the Environment (DfE) in a highly regulated, cost conscious business environment. The following notes summarize the conversation, but also include our observations and findings with respect to the issues discussed and the potential opportunities.

Regulatory Compliance

The term "compliance" for medical device manufacturers most often means compliance with FDA and other quality system requirements. "Environmental" compliance is a small subset of the overall compliance program at a highly regulated facility.

A number of regulatory challenges were identified at the June 24th meeting, however, there was neither an overwhelming cry for regulatory change nor a sense of tremendous burden. It is our observation that the EH&S staff at medical device manufacturers are lean, and that their responsibilities often include multiple facilities and/or corporate as well as facility responsibilities. They may not have the luxury to contemplate "bad" regulatory fits or regulations, as their time is principally occupied with conducting compliance activities (e.g., submitting forms, conducting inspections and training) and ensuring that environmental compliance obligations are met.

Environmental challenges that were identified include the following:

- Massachusetts prohibition against the treatment of hazardous waste, including elementary neutralization, without a permit;
- TURA reporting requirements for Persistent and Bioaccumulative Toxins (PBTs) for fuel burning activities (i.e., PACs and benzo(g,h,i)perylene);
- Inefficiency associated with updating and submitting the annual, or tri-ennial air source registration requirements on printouts, rather than on-line;
- Potential expansion and economic growth limitations resulting from stringent Volatile Organic Compound (VOC) emissions caps in air permits;
- Conflicting state/local reporting requirements associated with Underground Storage Tanks; and
- Challenges associated with the Department of Public Safety hoisting requirements.

In addition to the above-cited regulations, the medical device sector is likely to agree with draft recommendations submitted by the Massachusetts Biotechnology Council to the Romney Administration in the spring of 2004. These recommendations were designed to eliminate unnecessary or outdated regulatory requirements, and streamline or modify

certain regulations to better fit the operations and activities associated with FDA approved operations and activities.

As noted earlier, "compliance" is a priority of medical device manufacturers. In fact, the results of a recent survey (released at the Medical Design and Manufacturing East Convention held June 15-17, 2004 in New York City) found that "proactive regulatory compliance" ranked fifth, slightly behind cost improvement, but ahead of enhancing productivity and such challenges as Mergers and Acquisition (M & A) activity, technology transfer and scale-up. Environmental, health and safety regulatory compliance should clearly be a strong component of this emerging proactive compliance commitment.

State agency representatives expressed their commitment to following up on the identified environmental challenges. A few participants expressed the need for regulatory guidance to help the industry better understand their environmental obligations, especially during key expansion or growth phases of a company. Such guidance should target small and medium sized businesses.

Toxics Reduction/Design for the Environment

This topical discussion most effectively captured the interest of all participants. On the one hand, it gave voice to the frustration of EH&S representatives and product designers to address environmental issues early in the design process. On the other hand, it provided OTA with a much better understanding of the challenges, to date, associated with incorporating Design for the Environment (DfE) or "eco-design" principles into new product development.

What did we learn about the barriers to DfE? First, we heard that cost and timely access to markets are the key industry drivers. Environmental issues are often perceived as additional costs or delays in the design process. Second, we heard that EH&S representatives are generally not involved in the initial design or technology transfer processes. They are more likely to be included on a reactive, rather than proactive, basis. Third, we heard that company growth is often fueled by mergers and acquisitions, not by the development of new products. In other words, today's products were likely designed ten (or more) years ago, and opportunities to incorporate DfE principles are likely to be severely limited because of real or perceived challenges (i.e., costs, delays) associated with seeking FDA "approval for change." We heard that it may be cheaper for companies to risk an FDA fine than reopen the FDA approval and validation process. We spent significant time trying to understand whether this FDA impediment is real or perceived. Fourth, we heard that marketing departments are key drivers. They will react if consumers and customers express an interest in products with environmental attributes, which has generally not occurred to date in this sector.

What did we learn about opportunities for DfE? First, we heard that pressure from Europe is driving companies to consider environmental issues. Emerging – and potentially applicable – European Union standards include the Directive on the Restriction on the Use of Certain Hazardous Substances in Electric and Electronic

Equipment (RoHS) and the Directive on Waste from Electrical and Electronic Equipment (WEEE). RoHS restrictions on the use of such substances as lead, mercury, cadmium and polybrominated biphenyls does not currently apply to medical devices. The WEEE recovery, reuse and recycling targets and requirements will not apply to medical device equipment until after 2008. Additionally, a proposed Directive on Establishing Design Requirements for Energy-Using Products (EuP) is slated to soon become law. This directive will implement an integrated and far-reaching policy that will encourage – or force – manufacturers to design products with the environmental impacts in mind throughout their entire life cycle. It will apply to components, as well as final product. "If the executives, managers, design engineers and marketing departments look at WEEE and RoHs only as regulations that need to be followed, these companies will miss business benefits from creating less expensive, more reliable, longer lasting and higher customer loyalty products."[1] Second, we have learned that some companies are using DfE tools. For example, DePuy, a Johnson & Johnson company, has shared with OTA a Design for the Environment resource used by the company to develop their own DfE tool (see the reference in Appendix 4 beginning "Environmentally Conscious Design…"). We know that other leading medical device manufacturers are using similar tools. Third, the survey results from the Medical Design and Manufacturing East Convention suggest that companies are increasingly interested in filling the product pipeline, rather than growing through M & As. This provides more opportunity to consider environmental issues in the development of future products. Finally, the greening of hospitals – a major customer of medical devices – and the emergence of medical products as "life style products" may become drivers of greening activities over the years ahead.

Numerous suggestions were made to promote DfE principles, including the development of fact sheets and guidance on DfE; the development of a DfE tool/checklist; a case study showing the business case for DfE; and recognition programs and training for researchers, product designers and senior executives.

Efforts to Improve Operational Production Efficiency

We briefly discussed firm's efforts to improve operational production efficiency and minimize environmental impacts. The "success stories" presented by DePuy and Genzyme were clear examples of process changes that resulted in financial gain and improved environmental performance. Other such stories were slow to materialize during the Focus Group Meeting. There have clearly been efforts to retrofit lighting, conserve water and minimize energy usage. A number of medical device manufacturers have also reduced their Toxics Use Reporting Act (TURA) submittals over the years as a result of chemical substitutions and process changes. Concern was expressed, once again, that even the perception of the need to seek FDA "approval for changes" can derail production process changes that may provide environmental and cost improvements.

[1] "Get Ahead of Environmental Compliance," Circuits Assembly EMS Supplement, June 2004.

Efforts to improve operational efficiency are made to drive down costs and increase margins. They are likely implemented as total quality management, six sigma or lean manufacturing initiatives. EH&S participants at the meeting said that they do not generally become involved in process improvements, unless there is an environmental compliance challenge associated with it. It is therefore quite plausible that there is an "environmental" story to tell at each of the companies represented at the Focus Group meeting, but the participants were unfamiliar with the specific details and environmental benefits. In fact, corporate sustainability and environmental reports published by Baxter, Philips, Johnson & Johnson and Smith & Nephew make clear that significant reductions in air releases, solid waste disposal, and water and energy usage have occurred in these companies.

The group discussed opportunities to capture these stories, including the development of case studies or best practices by OTA. It was also suggested that an environmental award or recognition program might encourage firms to track and share these success stories.

Reuse/Recycling

The EH&S representatives at the Focus Group have limited involvement in in-house recycling programs. Plant programs to recycle paper, cardboard, scrap and containers are generally the responsibility of facilities, production or maintenance departments, according to our participants.

The conversation therefore centered more on potential recycling and end-of-life collection requirements associated with WEEE and RoHS, and the development and use of recyclable and reusable packaging. EH&S representatives at the meeting are often asked to track emerging regulations associated with the recyclability and labeling of components and equipment, and work with purchasing and quality control to ensure compliance with these standards.

Medical device manufacturers have a number of challenges associated with the recyclability of their devices. First, the devices often contain numerous components in which disassembly and labeling issues are complicated. Second, cost pressures and consumer drivers have led to a significant increase in the use of "disposable" medical devices over the last number of years. Some of these products now have electronics or batteries which must be captured and recycled prior to disposal. Third, the perception of contamination may limit the ability to easily develop recycling infrastructures. Recycling of vinyl products would be an example.

Suggestions for future activities/next steps included the development by OTA of a water conservation case study in the medical device sector; the development of recycling/reuse guidance for medical device manufacturers, especially smaller facilities; and a case study involving the collection of electronics in a disposable medical device product.

Supply Chain – Suppliers and Customers

The discussion regarding opportunities to enhance supply chain value through environmental excellence was interesting because many of the companies at the Focus Group meeting act as both customers and suppliers. They may manufacture or assemble their own products as Original Equipment Manufacturers (OEMs), as well as supply products or component pieces to other medical device manufacturers.

A few common themes emerged.

First, it became clear that efforts to "green" the supply chain are primarily driven by cost, access to overseas markets and directives on component restrictions and prohibitions, and quality system requirements to demonstrate compliance with the restriction. For example, Western Europe imported 57.9% of the medical devices exported from Massachusetts[2] in 2003. It is important for Massachusetts manufacturers to conform, and be able to demonstrate conformance on product assessment declarations, with applicable European standards and restrictions.

Second, the role of EH&S is generally confined to compliance and cost avoidance. While some EH&S representatives noted that they were involved in supplier evaluations, audits and product assessments, most participants observed that supply chain assessments and supplier declarations were the role and responsibility of the quality assurance/quality control department. Most participants further agreed that the use of environmental questionnaires or environmental audits, beyond verification of component restrictions, is not commonplace.

According to the BEACON study entitled "The Medical Device Industry in Southern New England's I-91 Corridor," small and emerging firms account for more than 80% of all medical device manufacturers. Focus Group participants agreed that there is value in providing compliance assistance to small "job shops" serving the medical device sector. There was some support for a recommendation to tailor an existing supplier screening program, which is currently offered by the Massachusetts Manufacturing Extension Partnership (MEP) to companies in the Commonwealth supplying products to the Department of Defense, to verify compliance with respect to environmental obligations at small suppliers.

Opportunities to more effectively integrate EH&S into the supply chain process appear to exist. First, some of the larger firms are registered to ISO 14001, the Environmental Management System Standard, and ISO 1485, the Quality Management System Standard for Medical Device Manufacturers, which provide an existing business and quality systems platform to green the supply chain. Second, medical device manufacturers increasingly rely on outsourced functions, and efforts to ensure environmental compliance and capture environmental efficiencies (e.g., energy conservation, reduced waste) can provide benefits. Third, leading companies increasingly view supply chain

[2] Medical Devices: Supporting the Massachusetts Economy, May 2004

excellence as a source of competitive advantage and value creation and utilize cross-functional teams, including EH&S representation, to capitalize on these benefits.

It is important to note the strong interaction between the plastics, precision metal, and electronics industries as suppliers to the medical device sector and the influential role the medical device sector could have on environmental performance in other industries – just by asking about the status of environmental programs. Recently, a healthcare system sent out an environmental questionnaire to its suppliers and was pleasantly surprised to find (a) a reasonable response rate and (b) that most suppliers had never been asked about their environmental programs.

The group agreed that opportunities were available to improve compliance and raise environmental awareness throughout the supply chain through written guidance materials and checklists, articles in key publications, and through expanded auditing or supplier verification processes.

Key Linkages

Tim Gerrity described the Worcester Polytechnic Institute (WPI) Bioengineering Institute (see http://www.wpi.edu/Academics/Research/BEI/) and the significant opportunities to link the medical device manufacturing sector with world-class hospitals and universities in the Commonwealth. While there are inherent challenges in trying to align private industry/manufacturers with decentralized not-for-profit organizations with highly educated employees on a common vision, there are ample opportunities to leverage current activities:

- For example, Dr. John Warner of the University of Massachusetts is a leader in the advancement of "green chemistry" principles in the biotechnology and pharmaceutical arena. Many of these principles have application to the development of new medical device products. Medical device companies rely heavily on universities and hospitals to develop new medical device technologies. On average, only 9% of revenue of medical device manufacturers is spent on research and development[3]. Consequently, many new product ideas come directly out of the laboratories of universities and hospitals.
- The Massachusetts Biotechnology Council is working with EOEA to streamline and strengthen environmental regulations as they pertain to biotechnology operations and the siting of new facilities. Many of these recommendations would be of benefit to the medical device manufacturing community.
- The U.S. EPA in Region 1 and Region 2 has initiated a "hospital initiative" that will focus on opportunities to improve environmental compliance at hospitals and improve environmental performance. Hospitals are an important customer of the medical device sector.

[3] BEACON Report

- The WPI Bioengineering Institute is committed to developing and providing tools to small and mid-sized medical device companies, and guidance in the area of applicable environmental, health and safety regulations is much needed. It is also committed to providing the curriculum to better prepare students for work in the medical device sector and arming researchers with appropriate tools.
- MassMEDIC is an increasingly powerful voice in the development of appropriate policies and legislation. Opportunities to collaborate with the Massachusetts MEP were also voiced at the Focus Group Meeting. Finally, opportunities to work with organizations in Europe should also be explored.

Participants agreed that leveraging these resources is important.

Next Steps

At the conclusion of the facilitated discussion, the participants reviewed the various topic categories and flip chart notes and prioritized issues and ideas. We have subsequently reviewed the suggestions and categorized them according to short-term and long-term actions (see Table 1 below). It is expected that the short-term steps would be completed within three months, or no later than October 1, 2004. With respect to long-term steps, OTA expects to initiate a dialogue with representatives from the FDA in the fall of 2004, and develop a strategic plan for assisting the medical device sector no later than November 1, 2004. The plan would be finalized and initiated in January 2005.

Table 1. Next Steps: Medical Device Manufacturers Project

Short Term Steps

- Send contact information for Focus Group participants to all participants.
- Draft and send letter to company CEOs who participated in the Focus Group meeting, thanking them for their companies' participation and commitment.
- Draft Focus Group Meeting Final Report and make widely available to members in the medical device sector.
- Communicate identified environmental regulatory compliance concerns (see Compliance section) to program managers at the Massachusetts Department of Environmental Protection and Department of Public Safety and follow-up with Focus Group participants.
- Follow up with certain medical device manufacturer participants who expressed an interest in an OTA site visit.

Long Term Steps

- Evaluate the FDA process for allowing certain changes to production processes and materials. Determine whether it is feasible to obtain guidance from FDA regarding existing provisions for making production and process changes (e.g., chemical substitutions, process changes, water conservation, waste recycling) without triggering the approval of change process. Alternatively, develop a compendium of allowable process changes, based on previous FDA determinations.
- Develop a plan to provide technical and regulatory assistance to the sector. The plan may include, but is not limited to, the following:
    (a) Regulatory guidance for startups;
    (b) Fact sheets on Design for the Environment (DfE) in the Medical Device sector, which defines DfE and demonstrates the business case for incorporating DfE;
    (c) Training plans and workshops, such as DfE and/or emerging European Directives, targeted to research and development professionals and senior executives;
    (d) Case studies (e.g., process change, greening the supply chain, innovative products with environmental attributes);
    (e) Opportunities for expanded recycling of manufacturing byproducts or collection take-back programs;
    (f) On-site technical assistance;
    (g) Strategic alliances with key organizations and associations.

APPENDICES

Appendix 1: Focus Group Participants

The following list includes attendees at the June 24, 2004 Focus Group meeting. Three participants, not listed here, had to cancel at the last minute due to conflicts and emergencies.

NAME	ORGANIZATION	TITLE
Timothy R. Gerrity, Ph.D.	WPI Bioengineering Institute	Director
Stephen Pritchard	Executive Office of Environmental Affairs	Chief Operating Officer
Jean Palmateer	DePuy Orthopaedics, Inc.	Director, Environmental Affairs
Robert Bleicher	Analogic Corporation	Environmental, Health and Safety Director
Mitch Campbell	Haemonetics Corporation	Environmental, Health and Safety Director
Paul Richard	Office of Technical Assistance	Director
Samuel Stein	Luxtec	General Manager
Jeffrey T. Silva, P.E.	Tyco Healthcare	Environmental Engineer
John Yannone	Design Mentor	Senior Designer
John Raschko, Ph.D.	Office of Technical Assistance	Team Leader
Joan Boegel	Genzyme	Associate Environmental Director
Lucy Servidio	Capaccio Environmental Engineering (representing TURA Planners)	Vice President
Pat Trudeau	Nypro, Inc.	Environmental, Health and Safety Specialist
Al Cotton	Nypro, Inc.	Vice President, Public Affairs
Wayne Sula	Massachusetts Manufacturing Partnership	Project Manager
Allan Cameron	Design Continuum	Principal
Jeffrey J. Joaquim, MS, CIH, CSP	Cytyc Corporation	Environmental, Health and Safety Manager
Thomas Balf	Nexus Environmental Partners (Facilitator)	Principal

Appendix 2: Organizations Contacted

The OTA contacted the majority of companies listed in the Harris Infosource Database or state environmental databases, listed in the appropriate SIC codes. With the exception of companies listed in the environmental databases, we did not have the contact information for the individual responsible for environmental affairs. Additionally, many of the firms contacted are small firms or included medical device SIC as one of many business classifications codes, and expressed interest in the subject but did not believe that they could provide significant value to the Focus Group Meeting. The following companies and organizations were contacted as part of this initiative.

Abiomed Incorporated	ACMI Corporation	Agilent Technologies
Amatech Corporation	Analogic Corp	Angel Guard Products
Aspect Medical Systems, Inc.	Associated Industries of Massachusetts	Avitar Technologies
Bayer Healthcare Diagnostics	Becton Dickinson & Co.	BD Biosciences
Bionostics	Boston Brace	Boston Medical Products
Boston Scientific Corporation	Burke Medical Equipment	C.R. Bard, Inc.
Cambridge Heart, Inc.	Candela Corporation	Capaccio Environmental Engineering
Cortek, Inc.	Cyanosure, Inc.	Cytyc Corp.
Department of Environmental Protection	DePuy Orthopaedics, Inc.	Design Continuum
Design Mentor	Dosco Sheet Metal	ECI Biotech
Environmental Protection Agency	Flexcon	Fosta – Tek Optics
GE Osmonics, Inc.	Genzyme Biosurgery	Graphic Controls Corp.
Haemonetics Corp.	Hightech Prevision Molding	Hologic, Inc.
Honeywell	IDEO Design	Intech, Inc.
Interactive Motion, LLC	Inverness Medical Innovations, Inc.	J&S Medical Associates, Inc.
Karl Storz	Isomedix	Linos Photonics, Inc.
Ludlow Technical Products	Luxtec Corporation	Mack Prototype
Manta Design	Massachusetts Manufacturing Partnership	MassMedic
Med Source Technologies	Medtronic	Mettler Toledo Ingold
Micron Medical Products	Miniature Tool & Die	Mira Inc.
MR Resources	NEMI Scientific	NMT Medical, Inc.
Nova Biomedical Corporation	Nypro	Omniglow Corporation
Optim, Inc.	Palomar Medical Technologies, Inc.	Philips Medical Systems
PLC Medical Systems, Inc.	Precision Optics, Inc.	Prosthetics and Orthotics Laboratory
Radius Medical Technologies	Ranfac Corporation	Schott Fiber Optics, Inc.
Smith & Nephew Endoscopy	Starkey Laboratories	STD Manufacturing Inc.
Steris Isomedix, Inc.	Tevnan & Tevnan	Techman International Corporation
Texatron	Thermo Electron	TNCO, Inc.
Tyco Healthcare	Venture Tape Corporation	Vision-Sciences, Inc.
Vita Needle	Winchester Laboratories, Food and Drug Administration	WPI Bioengineering Institute
Zoll Medical Corporation		

Appendix 3: The Medical Device Industry In Massachusetts

The medical device manufacturing industry is a significant contributor to the Massachusetts economy. This sector includes approximately 217 manufacturing establishments with 20,365 employees, a payroll of $1.2 billion and shipments valued at $5.0 billion[4]. According to a ranking scheme employed by UMass Boston, Massachusetts ranks second, behind Minnesota and before California and Illinois, when assessing employment and payroll by absolute and per-capita size. The industry was a stabilizing influence on the Massachusetts' economy during the difficult economic times during the last few years.

The three sectors -- surgical and medical instruments; electromedical and electrotherapeutic apparatuses; and surgical appliances and supplies -- that are the focus of our project represent nearly 70% of the medical device employment in Massachusetts. These sectors vary considerably, however. For example, the average surgical and medical instrument plant employs 77 workers, whereas the average electromedical plant employs 197 workers.

There are two key business issues of particular relevance to this Project.

First, important linkages exist between medical device manufacturers and manufacturers of electronics, producers of precision metal components, and plastics manufacturers. These companies "supply" the medical device industry with key materials and parts for final product manufacture and assembly operations. According to the UMass Report, for every dollar of output in the medical device industry in Massachusetts, 45 cents worth of materials and services are purchased from other industries. Alternatively, many companies in Massachusetts operate under multiple SIC codes as a precision metal manufacturer or textile manufacturer for which a significant portion of the business is medical devices.[5]

Second, the medical device industry in Massachusetts exports more than half of its output to other states and countries. Fifty-nine percent of the medical devices exported from Massachusetts were sent to Western Europe in 2001. European Union environmental requirements in the form of bans or prohibition on the use of certain chemicals, as well as more stringent environmental requirements passed by other countries and states, may affect the sale of products from Massachusetts manufacturers.

The operations of companies listed as medical device manufacturers include a wide range of facility types, including:

- Corporate headquarters
- Research and development laboratories
- Pilot production plants

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[4] *Medical Devices: Supporting the Massachusetts Economy*, Alan Clayton-Matthews, Rebecca Loveland, University of Massachusetts Boston, 2004 (see Attachment 2)

[5] Harris Guide Listings

- Manufacturing plants
- Assembly plants

Some mid-sized and larger companies have outsourced their manufacturing to other states or countries or have their products contract manufactured.

General Characterization: Surgical and Medical Instruments & Apparatus (SIC 3841/NAICS 33912)

According to the Harris Full Profile Reports, there are 122 companies in Massachusetts listing SIC Code 3841 as a primary or secondary SIC codes. These facilities are located in 66 communities throughout the Commonwealth. Many of the largest medical device manufacturers in Massachusetts are listed in this SIC code.

Products: The types of products manufactured by these companies may include the following:

• Anesthesia equipment	• Balloon pumps	• Blood donor scales
• Blood gas processing and monitoring systems	• Cardiac assist products	• Catheters
• Diagnostic equipment	• Endoscopes	• Heart assistance devices
• Hypodermic needles	• Infusion pumps	• IV infusion stands
• Medical alert systems	• Medical and surgical labware	• Medical monitors
• Medical needles	• Medical tubing packs/assemblies	• Medical wire products
• Monitor suspension systems	• MRI equipment	• Plastic fabricating (e.g., flow control, eyelets)
• Plastic medical parts (injection molding)	• Prototype and development machining	• Stethoscopes
• Surgical devices	• Surgical instruments	• Surgical platelet harvesting equipment
• Syringe pumps	• Tracheotomy products	• Vascular medical devices

Operations and Activities: The Harris profile data provided a snapshot of processes and operations for each listed medical device company. Common processes, as listed in the Harris Guide, included the following:

- Assembly
- Coating operations
- Fabrication of metal parts
- Fabrication of fasteners and pins (e.g., eyelets)
- Fiber optics manufacturing
- Machine shop operations (e.g., precision machining)
- Metal stamping
- Molding (rubber and plastic)
- Pharmaceutical preparation
- Pressed and blown glassware
- Prototyping
- Research and development
- Tool and die operations

Massachusetts Environmental Regulatory Compliance Information:

Hazardous Waste Generators: According to the EPA database, 24 hazardous waste generators are listed for NAICS 339112. Of these, 7 are large quantity generators, 7 are small quantity generators, 3 are conditional exempt small quantity generators (CESQG) and 7 facilities are no longer generating hazardous waste. Conditionally exempt small quantity generators (CESQG) are generally not identified in the EPA database, as they are regulated only by the State.

Air Permits: According to the Massachusetts Department of Environmental Protection, the state has issued 22 "minor" permits for facilities operating in Massachusetts in this NAICS category. These permits are issued for either combustion facilities or volatile organic compounds (VOC) emissions. Some permits are "minor" – in that the potential to emit is lower than "major source" thresholds -- and some companies operate under "synthetic minor" permits because they have accepted an enforceable limitation to operate below the major source thresholds.

Toxic Release Inventory Filers: According to EPA's database, nine facilities have filed Toxic Release Inventory Forms for SIC Code 3841 for the reporting period 2001. A total of 16 companies/facilities have filed reports since the inception of the program.

Toxic Use Reduction Act Filers: Only three companies filed TURA reports for the most recent reporting period (2001). According to the TURI database, 13 companies have reported for SIC Code 3841 since 1990.

General Characterization: Orthopedic, Prosthetic and Surgical Appliances/Supplies (SIC 3842/NAICS 339113)

According to the Harris Full Profile Reports, there are 81 companies in Massachusetts listing SIC Code 3842 as a primary or secondary SIC code. These facilities are located in 63 communities throughout Commonwealth.

Products: The types of products manufactured by these companies may include the following:

- Artificial limbs
- Body armor
- Braces
- Catheters
- Dental abutments
- Dental prosthetics
- Foam products
- Hand splints
- Hearing aids
- Hypodermic needs
- Laser equipment
- Laser safety equipment
- Medical tubing
- Orthopedic shoes
- Orthotics
- Patient positioning devices
- Prosthetics
- Pumps for CAT scans
- Safety products
- Seating systems
- Soft orthopedic braces
- Sponges
- Stainless steel equipment
- Surgical implants
- Surgical products made of injection molded plastics
- Surgical sponges
- Tactile aids and listening devices
- Wheel chair lifts
- Wheelchair cushions
- Wheelchairs and ambulators

Product Operations and Activities: The Harris profile data provided a snapshot of processes and operations for each listed medical device company. Common processes included the following:

- Machine shop operations (e.g., precision machining)
- Metalworking and heat treating
- Paper and cloth manufacturing
- Plastics manufacturing (tubing, injection molding)
- Repair shop activities
- Weaving and textile manufacturing

Massachusetts Environmental Regulatory Compliance Information:

Hazardous Waste Generators: According to the EPA database, only four hazardous waste generators are listed for NAICS 339113. One of the facilities is a large quantity generator.

Air Permits: According to the Massachusetts Department of Environmental Protection, the state has issued two "synthetic minor" permits for facilities operating in Massachusetts in this NAICS category.

Toxic Release Inventory Filers: According to EPA's database, five facilities have filed Toxic Release Inventory Forms for SIC Code 3842 for the reporting period 2001. A total of 5 companies/facilities are reported as filing since the inception of the program.

Toxic Use Reduction Act Filers: Only two facilities filed TURA reports for the most recent reporting period (2001). According to the TURI database, only two facilities have reported for SIC Code 3842 since 1990.

General Characterization: Electromedical and Electrotherapeutic Apparatus (SIC 3845/ NAICS 334510)

According to the Harris Full Profile Reports, there are 62 companies in Massachusetts listing SIC Code 3845 as a primary or secondary SIC code. These facilities are located in 49 communities throughout Commonwealth.

Products: The types of products manufactured by these companies may include the following:

- Blood processing equipment
- Cat Scanners
- Control communication units for handicapped
- EKG sensors
- Electronic audiological equipment
- Electronic biomechanical devices
- Electronic dialysis machines and supplies
- Endoscopes
- External pacemakers
- Heart assistance devices
- Imaging (except X-ray)
- Imaging (X-ray) apparatus and tubes
- Laboratory instruments
- Laser systems
- Medical cameras and light sources
- Microscanners
- Monitoring systems (e.g., anesthesia)
- Nuclear imaging equipment

Operations and Activities: The Harris profile data provided a snapshot of processes and operations for each listed medical device company. Common processes including the following:

- Parts cleaning
- Coating
- Fabrication of metal parts
- Machine shop operations (e.g., precision machining)
- Optics/glassware production
- Plastic product manufacturing
- Research
- Welding

Massachusetts Environmental Regulatory Compliance Information:

Hazardous Waste Generators: According to the EPA database, only two hazardous waste generators are listed for NAICS 334510. Both facilities are listed as small quantity generators.

Air Permits: According to the Massachusetts Department of Environmental Protection, the state has issued two "synthetic minor" permits for facilities operating in Massachusetts in this NAICS category. One of these facilities had a "restricted emission status" limitation on the release of VOCs.

Toxic Release Inventory Filers: According to EPA's database, three facilities have filed Toxic Release Inventory Forms for SIC Code 3845 for the reporting period 2001. A total of 5 companies/facilities have filed reports since the inception of the program.

Toxic Use Reduction Act Filers: Only one facility filed TURA reports for the most recent reporting period (2001). According to the TURI database, only one company has reported for SIC Code 3845 since 1990.

Appendix 4: Resource Materials

The following list includes primary research materials and documents used in preparing the Background "Issues Paper" and this "Final Report."

"An Act Relative to Safe Alternatives to Toxic Chemicals," Bill #MA03RHB 4642, filed in Massachusetts on April 05, 2004.

"Biotechnology Regulatory Guide for Communities," Massachusetts Biotechnology Council, 1998.

"Choosing to Lead: The Race for National R & D Leadership & New Economy Jobs" The Massachusetts Technology Roadmap, Part II: Strategic University-Industry Alliance Opportunities. A collaborative research project of Mass Insight Corporation and Battelle.

"Environmentally Conscious Design Support Tool in Early Stage of Product Development: Quality Function Deployment (QFD) for Environment (QFDE)," Keijiro Masui, *ECP Newsletter* No. 20, Japan Environmental Management Association for Industry (JEMAI). www.jemai.or.jp/english/dfe/pdf/20_4.pdf

"Get Ahead of Environmental Compliance," Pamela Gordon, *Circuits Assembly Magazine*, EMS Supplement, June 2004,

"Medical Devices Go Green," *Medical Devicelink*, the platform website for the medical device industry, March 2002.

"Medical Devices Made with Polyvinylchloride (PVC) Using the Plasticizer di-(2-Ethylhexyl)phthalate (DEPH); Draft Guidance for Industry and FDA," Food and Drug Administration, Center for Devices and Radiological Health," September 6, 2002.

"Medical Devices: Supporting the Massachusetts Economy" Alan Clayton-Matthews, University of Massachusetts Boston and Rebecca Loveland, University of Massachusetts Boston. Written for the Massachusetts Medical Device Industry Council. May 2004.

"Public Health Notification: PVC Devices Containing the Plasticizer DEHP," Food and Drug Administration, July 12, 2002

"Q & A with Nicholas Brathwaite, Chief Technology Officer, Flextronics Corporation," *Circuits Assembly*, May 2004

"RCRA Representative Handler Detail Report" provided by the Environmental Protection Agency, based on the RCRAInfo Database. Run in June 2004, it includes the identification of sites in the appropriate NAIC codes that have an EPA/DEP RCRA Generator Identification number.

"The Greening of Standardizations (Designed medical devices with environmental concerns in mind)," Richard Moore, *Medical Technology*, April 01, 2001

"The Medical Device Industry in Southern New England's I-91 Corridor: Potential for Growth," Conducted by BEACON in cooperation with the Regional Technology Corporation of Western Massachusetts and its affiliate network, the BioEconomic Technology Alliance. June 2004.

Clinica: World Medical Device & Diagnostic News

Conference Agenda: Medical Device Manufacturing (MDM) Conference, June 14 – 17, 2004 New York City

Directive on the Restriction on the Use of Certain Hazardous Substances in Electric and Electric and Electronic Equipment (RoHS), European Parliament

Directive on Waste from Electrical and Electronic Equipment (WEEE), European Parliament

Envirofacts Data Warehouse Reports, available on line from the U.S. EPA

Facility Registry System (FRS), U.S. Environmental Protection Agency public database provided facility detail reports for selected SIC codes.

Harris Infosource. Provides names of companies and contact information for management representatives in SIC Codes 3841, 3842 and 3845.

Medical Device Daily, the Daily Medical Technology Newspaper

Medical Devicelink, website for the medical device industry.

Proposed Directive on Establishing Design Requirements for Energy-Using Products (EuP), European Parliament

Toxics Release Inventory Reports, available on line from the U.S. EPA

TURA Reports, available on line from the Toxics Use Reduction Institute

Web pages for various medical device manufacturers, especially those that product annual environmental reports (e.g., Baxter Healthcare International, Smith & Nephew, Johnson & Johnson, Philips Medical)

Web pages of the U.S. Food and Drug Administration Center for Devices and Radiological Health

Appendix 5: Environmental Issues in the Medical Device Sector

Based on research and interviews with key stakeholders, the following environmental topics were presented as proposed topics at the June 24, 2004 Focus Group Meeting. Some of these issues are specific to the medical device sector, while some topics are relevant to a broad spectrum of manufacturers in the Commonwealth. The topics are presented below as questions to be discussed at the meeting. At the beginning of the focus group meeting, we prioritized topical areas and directed the discussion based on the priorities of the group.

1. Are companies incorporating environmental criteria into the design of products? What are the barriers to "green product design" and the use of alternative materials and innovative processes? Relevant issues may include:

    a. Customer requirements

    b. FDA approval considerations

    c. Risk aversion/cost sensitive culture

    d. Use of life cycle assessment methodologies

    e. Green procurement

2. Is the implementation of an Environmental Management System (EMS) an emerging "requirement" of doing business in this sector? Relevant issues may include:

    a. Required to do business in certain countries, regions?

    b. Required by customers?

    c. Imposed on suppliers?

    d. Is this a problem for mid-size to smaller companies? If yes, why?

3. Are there opportunities to improve or streamline state regulations through guidance, regulatory revision or statutory change?

4. What operations and processes that result in significant environmental impacts are ripe for competitive enhancements, based on potential financial savings and marketplace or regulatory drivers. Relevant issues may include:

    a. Energy efficiency

    a. Water conservation and water reuse

    b. Coating operations

    c. Plating operations

d. Degreasing, washing/rinsing and sterilizing operations

e. Cooling systems

f. Adhesives and assembly operations

5. What waste streams are most likely to pose environmental, health and safety challenges or present opportunities to reduce, reclaim or recycle? Relevant issues may include:

    a. Wastewater constituents/characteristics

    b. Hazardous wastes (e.g., solvents)

    c. TURA reported releases

    d. Solid wastes (e.g., reusability of transport packaging)

6. How is the medical device industry responding to – and prepared for – the restricted use or prohibition of certain materials and substances in packaging and devices? (e.g., The Waste Electrical and Electronic Equipment (WEEE) and Restrictions on Hazardous Substances (RoHS) issued by the European Parliament). Relevant issues may include:

    a. Inks, dyes

    b. Adhesives

    c. Stabilizers (e.g., lead)

    d. Plastics (e.g., PVC) and plasticizers (e.g., DEHP)

    e. Metals (e.g., lead, cadmium, mercury)

7. How is the industry responding to regulatory and marketplace pressures for the recycling of components or devices? Relevant issues may include:

    a. Marking of plastic parts for recycling

    b. Design for disassembly

    c. Electronics

    d. On-site recycling

8. What is the “state” of environmental reporting?

    a. State and Federal reporting issues (e.g., TURA, TRI, PBTs, Tier II)

    b. Product assessments for customers

e. Supplier declarations and testing

f. Necessary or unnecessary burden

9. What are potential key linkages in addressing environmental issues?

    a. University research centers

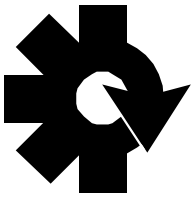
    b. Suppliers

    c. Customers

    d. State agencies

Appendix 6: Focus Group Agenda

Executive Office of Environmental Affairs



OFFICE OF TECHNICAL ASSISTANCE

Setting Your Agenda for Environmental Performance:

A FOCUS GROUP WITH MASSACHUSETTS MEDICAL DEVICE MANUFACTURERS

June 24, 2004
8:00 AM – 1:00 PM

Nypro Inc., Old Mill Conference Room

8:00	**Registration and Continental Breakfast**
8:30	**Welcome/Introductions**
	• *John Raschko, Ph.D., OTA*
	• *Steve Pritchard, COO, Executive Office of Environmental Affairs*
	• *Paul Richard, Director, OTA*
9:15	**Company Success Stories**
	• *Jean Palmateer, Director Environmental Affairs, DePuy Orthopaedics, Inc.*
	• *Joan Boegel, EH&S Manager, Genzyme, Inc.*
9:45	**Break**
10:00	**Facilitated Discussion**
	• *Facilitators: Thomas Balf, Nexus Environmental and John Raschko, Ph.D., OTA*
	• *Discussion of specific topics identified in Issues Paper and raised by participants*
12:00	**Lunch**
1:00	**Adjourn**