**HEALTHCARE PACKAGING AND MEDICAL WASTE STRATEGIES:**

**DYNAMIC OPPORTUNITIES IN AN EVOLVING WORLD**



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**HEALTHCARE PACKAGING AND MEDICAL WASTE**

**UNDERSTANDING THE MEDICAL WASTE STREAM, REGULATORY COMPLIANCE TRENDS AND IMPACT ON HEALTHCARE PACKAGING**

## PACKAGING AND THE GLOBAL WASTE STREAM

Environmental impact has become an increasingly important factor in design and specification of medical packaging across the world. Safe and cost effective disposal of the package after use, is an important consideration when selecting materials and deciding on a final package design. Integrating environmental impact with sterility assurance, process validation, shelf life and regulatory compliance requirements will be essential in not only meeting global legislative demands, but in providing patients and health care providers with an optimum packaging solution . This white paper will provide an understanding of the evolving medical waste stream, legislative demands, and proper use of an objective Life Cycle Analysis ('[cradle](http://en.wiktionary.org/wiki/cradle)-to-[grave](http://en.wiktionary.org/wiki/grave) analysis including investigation and evaluation of the environmental impacts of a given product that addresses each phase of packaging from extraction (raw materials), to processing (manufacture of finished package), to supply chain (transport of goods), to disposal).

**INTRODUCTION: OVERVIEW OF GLOBAL WASTE STREAM**

In order to best understand medical packaging and it’s impact on the medical waste stream, it is first important to understand the relationship to the overall waste stream in the U.S. and that of other industrialized nations. The United States for example, spends over $50 billion dollars to manage industrial, municipal, electronic, construction and medical waste streams. From a volume perspective, well over 13 billion tons of waste were produced on an annual basis according the Environmental Protection Agency in 2009. That translates between two and six cents per pound for disposal. Regulated medical waste (e.g., infectious, biohazardous or red bag waste), represents less than 15% of the overall waste stream in hospitals, and costs anywhere from 19 to 40-plus cents per pound for proper disposal; hazardous waste (e.g., chemicals, some types of batteries, mercury, solvents) costs run between $1 to $6 per pound for disposal, and nuclear waste from certain medical applications are even higher. Health concerns with proper management of medical waste due to the potential spread of infectious disease however is the most important point of differentiation in comparison to the municipal and to some degree industrial waste streams.

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**MEDICAL WASTE STREAM**

The next decade will see dramatic change in ways that hospitals handle and dispose of medical waste on a global basis. Prompted by factors of , regulation, cost and the need to address social responsibility, manufacturers, hospitals and clinicians will drive unparalleled change in how products / packaging are used, and ultimately disposed of. Understanding each of these factors will be critical to the successful development of sound strategies that best meet the overall needs of the patient and clinician, as well as environmental stewardship with waste management, corporate policy and legislation.

**UNITED STATES REGULATIONS AND MEDICAL WASTE**

Healthcare packaging is clearly differentiated from many other industries based on stringent requirements associated with patient and clinician safety. Sterility, pharmacological efficacy, and specific delivery systems are not only essential to safety, but are literally a matter of life and death. As a consequence, environmental regulations were historically slow to change with healthcare packaging, particularly in comparison to retail and industrial industries. The corporate movement to embrace environmental strategies and public perception over the past decade is now evolving to include more applications with Healthcare packaging. Due to the increasing efforts at hospitals to improve segregation of red bag or infectious waste from the general waste stream, more volume is now entering the municipal waste stream. To better understand this evolution, it will be important to first understand the dramatic changes that occurred over the past several decades.

Medical waste management in the United States became a national crisis after medical waste washed up on several East Coast beaches in the late 1980s, raising concern over potential health hazards to the general public. This prompted Congress to enact the Medical Waste Tracking Act (MWTA) of 1988, which forced accountability in handling infectious waste. Hospitals and waste haulers were levied severe penalties if waste was not managed appropriately and within strict legislative guidelines that focused on cradle to grave accountability between point of creation and final disposal. Specifically, the Solid Waste Disposal Act covered the following:

* Defined medical waste and established which types of medical wastes would be subject to program regulations.
* Established a cradle-to-grave tracking system utilizing a generator-initiated tracking form.
* Required management standards for segregation, packaging, labeling and marking, and storage of the medical waste.
* Established record keeping requirements and penalties that could be imposed for mismanagement.

The regulations for this two year program initially went into effect on June 24, 1989 in four states (New York, New Jersey, Connecticut, Rhode Island) and Puerto Rico. During this time, EPA also gathered information and performed several studies related to medical waste management. The MWTA and EPA's associated program served to focus attention on the medical waste issue and provided a model for some states and other federal agencies in developing their own medical waste programs. The MWTA also required EPA to examine various treatment technologies and to assess their ability to reduce disease causing potential of medical waste.

The technologies that EPA examined in 1990 included:

* incinerators and autoclaves (both onsite and offsite)
* microwave units
* various chemical and mechanical systems

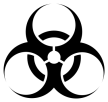
From the information gathered under the MWTA and EPA's concurrent investigations, EPA concluded that the disease-causing potential of medical waste is greatest at the point of generation and naturally tapers off after that point. Thus, risk to the general public of disease caused by exposure to medical waste is likely to be much lower than risk for the occupationally exposed individual.

MWTA further defined medical waste as "any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals." This definition includes, but is not limited to:

* blood-soaked bandages
* culture dishes and other glassware
* discarded surgical gloves
* discarded surgical instruments
* discarded needles used to give shots or draw blood (e.g., cultures, stocks, swabs used to inoculate cultures)
* removed body organs (e.g., tonsils, appendices, limbs)

There are currently four (4) categories of medical wastes:

* Infectious,



* Hazardous,



* Radioactive,



* Other general wastes from healthcare and medical facilities.

The greatest amount of concern is related to infectious, hazardous, and radioactive wastes, which represent only a small portion of all medical waste generated each year. Although the EPA does provide some oversight of medical waste storage and disposal from the Federal level, the majority of medical waste is regulated on a state or local level. The exception to this rule is radioactive waste, which is regulated by the NRC (Nuclear Regulatory Commission) and emissions from medical incinerators, which are regulated by the EPA. Other federal organizations regulate other aspects of medical waste disposal. For example, the DOT (Department of Transportation) has regulations on the transport of medical waste, and OSHA Occupational Health and Safety Administration) has regulations on the presence of medical waste in the workplace, though attention to the issue of Medical Waste management has drawn much attention from US officials in the recent past, the importance of the topic is not limited to the national stage.

**INTERNATIONAL REGULATIONS WITH MEDICAL WASTE**

Many other countries are pushing for regulations that will also help to drive global change. For example, hospitals in Austria, Germany, the Netherlands, Luxembourg and Scandinavia are reducing their use of PVC. A Directive on Packaging & Packaging Waste, which was passed in December 1994 to "harmonize" the European Union's 15 members' individual laws, also includes Medical and Pharmaceutical packaging under European Directive 94/62. Eastern Europe is already looking to tax and regulate packaging, while several Asian countries are implementing their own versions of "producer responsibility, very similar to that of the German Green Dot legislation. In 1991 the German government adopted a packaging ordinance, the foundation of which is the belief that the companies that design, produce, use, and profit from packaging should be held financially responsible for the disposal of packaging. The ordinance requires companies to pay according to both the volume, weight or type of packaging they use, which then incentivizes those organizations to reduce packaging and use safer materials. To simplify logistics, most companies partnered with Duales System Deutschand (DSD) to collect packaging and safely reuse, recycle or dispose of it for a fee. DSD is commonly called the Green Dot program; the signature green dot will appear on packaging with companies that actively support these efforts. Prior to the ordinance, packaging waste in Germany was increasing at 2 -4 % each year. Between 1991 and 1995, packaging waste decreased by a total of 14%; in comparison, waste in the United States increased by 13%. The Green Dot program continues to this day, with a focus on collection, recovery and recycling efforts. By 2001, enabled recovery rates of between 60 and 90 percent for glass, paper , cardboard, packaging waste, metals and biowaste were realized. Healthcare packaging was given limited exemptions in the past, but this is changing based in large part by distinguishing a good portion of packaging applications from the infectious waste stream at hospitals. Argentina and the Philippines, represent two countries leading efforts in developing substitutes for mercury-based medical devices with safe, accurate and affordable alternatives. Significant steps to implement and strengthen their national mercury-free health care policies are underway. The aggressive efforts by the Health Ministries in both countries are seen as bolstering initiatives in many other countries including Brazil, Chile, China, India, Mexico and South Africa where hospitals and health care systems are also switching out their mercury-based medical devices in favor of safer, accurate and affordable alternatives.

**COST** **AND TREATMENT OF MEDICAL WASTE**

There are about 10,000 private waste management companies in the US, with aggregate annual revenue of $50 billion. The most common services rendered by the industry include waste collection, treatment, disposal, remediation, and recycling. The wastes processed include solid wastes, low-level radioactive wastes, and liquid wastes. Current trends in medical waste management are evolving rapidly, in large part due both Federal and State regulations. Incineration of medical waste will continue to come under scrutiny across the globe. In the U.S., legislation will drive much of the direction with a two pronged approach. At the Federal level, the primary driver will focus on atmospheric effluent generated as a byproduct of the incineration process. (The Federal Clean Air Act restricts emission of toxins including furans and dioxins). As regulations tighten over time, many incineration operations will be faced with costly upgrades and installations of scrubbing systems, adding significant cost to the process, which could be prohibitive. At the state level, regulation of fly ash, also a byproduct of the incineration process, could increase insurance costs due to potential liability and non compliance with RCRA (Resource conservations and recovery act), which could also be prohibitive. As hospitals look to control cost, alternatives to incineration are being explored with significant interest in pursuing disinfection of RMW, via several methodologies including autoclave, microwave and chemical disinfection processes. Autoclave technology is most encouraging and taking a foothold in the western United States, particularly in California, noted as a leading state in regulating environmental policies. In order to plan for future trends, it will be important to understand the basic technologies moving forward.

The Gross National Trash statistics developed by Joel Makower in 2009, a leading authority on Waste Management in the United States, demonstrated that every pound of trash that ends up in a municipal landfill, will have at least 40 pounds of upstream waste created by the industrial and manufacturing processes; an important consideration when developing packaging, and a key element that will need to be addressed as part of a thorough Life Cycle Analysis. In 1960 the United States produced 88 million tons of municipal solid waste or 2.68 pounds per person per day. By 1990 in spite of major recycling efforts, those figures rose to 4.55 pounds per person per day. These figures are growing at even much faster rates due to the growth of single use sterile medical devices over the past two decades. Overall hospital waste very often represent the largest contribution in overall volume to the local municipal waste stream and landfill. Other Industrial nations (U,N, Statistics Division, indexmundi.com) are as follows: Australia (2.70), Japan (2.58), Canada (1.79) and China (.70). Medical waste, or red bag waste (waste that is systematically regulated based on the potential to spread infectious disease) represents a relatively small percentage of the total, but often captures much of the public concern for obvious reasons, is undergoing a major evolution. Understanding the factors driving these changes will again be critical to a good package design that will meet both existing and future needs of patients, clinicians and the public in general. Despite these efforts related to policy, common practices in health care continue to pollute the environment and have the potential to harm society and human health. For example, Mercury, other heavy metals and endocrine disrupters are present in many health care products and threaten the health of patients, workers and communities. Incineration of medical wastes can produce dioxins, and can disperse these toxins into the atmosphere as effluent from the incineration process, or as fly ash that ends up in landfills. Both dioxin and mercury are persistent, bioaccumulative toxins that can pose threat to humans and the environment. According to the EPA’s 2009 Dioxin Reassessment, the average dioxin level in Americans is now at, or exceeding levels that cause health effects including cancer, birth defects, damage to immune, neurological and hormonal systems. Dioxin is formed as a by-product of several processes, including the incineration of wastes containing chlorinated materials such as PVC (polyvinyl chloride). PVC was historically used and continues to be used in packaging applications, particularly with Pharmaceuticals, blood bags, and many disposable products. Many hospitals continue to incinerate PVC containing materials as part of their existing waste management processes, producing by product toxins in both air and landfill environments. Plasticizers such as phthalates, (used in PVC plastics) are being evaluated for their effects on hormones such as estrogen. These substances have unproven but potentially harmful effects to the human reproductive system. Other materials such as latex, now also represent a growing concern. It has been estimated that 8% – 12% of regularly exposed health care clinicians are sensitive latex. (NIOSH, 1997)

# A trend is continuing to evolve worldwide with the regulation of medical waste, and in particular infectious medical waste. After the closing of more than 3,600 medical waste incinerators in the United States since 1995, the industry was faced with finding alternatives to incineration. A growing number of facilities now turn to service companies, autoclave methods, and even some microwave solutions to meet the steady flow of medical waste generated by a growing health care and pharmaceutical industry.

**PRIMARY REGULATED MEDICAL WASTE MANAGEMENT PROCESSESS**

The key concern with regulated or infectious waste will reflect the potential for spread of infectious disease. The following 5 technologies are effective methods in rendering infectious waste as being non-infectious waste via effective bacteria kill.

* Incineration
* Autoclave (covered in more detail under sterilization chapter)
* Mechanical/Chemical Disinfection
* Microwave
* Irradiation ( covered in more detail under sterilization chapter)

Treated waste from these processes can be disposed via general waste in municipal landfills. In the past, treatment of both regulated and non regulated medical and hospital waste was managed on-site at hospitals or with dedicated medical waste facilities. The expense and regulation of these facilities, however, prompted organizations to hire private companies to collect, treat, and dispose of medical waste and the percentage of medical organizations that perform their own treatment and disposal is expected to decrease in the future.

To ensure that each treatment method provides the proper environment for the destruction of biologicals, test packages containing a microbiological spore test indicator are regularly used to test the effectiveness of the treatment methods. Microbiological spores are the most difficult of biologicals to destroy, so when the test package cannot be cultured after treatment, the waste is considered properly treated. In treatment methods where shredding or maceration is employed, the test package is inserted into the system after the shredding process to avoid physical destruction. The test package is then retrieved from the waste after treatment.

## Incineration

According to the EPA, 90% of medical waste is incinerated. The EPA also reported that at least 20% of medical waste is plastic, including the potential production of harmful chemicals that are released via the combusting process. The majority of older medical waste according to a number of industry surveys over the past decade, indicate that existing incinerators contain limited pollution control equipment, allowing potential release of harmful emissions including furans and dioxins. The waste generally passes through the incinerator on a belt, and because most medical waste can be incinerated, the waste is not sorted or separated prior to treatment. Incineration has the benefit of reducing the volume of the waste, sterilizing the waste, and eliminating the need for pre-processing the waste before treatment. The resulting, incinerated waste can be disposed of in traditional methods, including landfills. The downside of incineration is potential pollution from emissions generated during incineration as well as heavy metal content often found in the residual fly ash. The EPA has stringent requirements on emissions from medical incinerators. The incineration process can be applied to almost all medical waste types, including pathological waste, and the process reduces the volume of the waste by up to 90%.

Modern incinerators can provide a secondary benefit by harnessing the heat created by the incineration process to power boilers in the facility. The flames in the primary chamber can ignite fossil fuels in a secondary chamber and power facility boilers.

The largest concern associated with incineration is pollution. As new federal and state emission regulations are instituted that have more stringent requirements, medical incinerators are often not being replaced at the end of their service life. Over time, the amount of waste being incinerated will be reduced as other technologies, including autoclave, and chemical disinfection replace on-site incinerators. Another concern is related to the content of incinerator ash. As incinerators are designed or retrofit with pollution prevention equipment, more of the potentially toxic chemicals that previously ended up in emissions now remain in the ash. Incinerator ash is generally disposed of in landfills, and little data is available on the effects of ash on the environment. As additional requirements are added to the emissions for medical waste incinerators, the cost of incinerating medical waste increases, and alternative treatments have impacted overall volume and market share.

## Autoclaves

Autoclaves are closed chambers that apply both heat and pressure, and sometimes steam, over a period of time. Autoclaves have been used for nearly a century to sterilize medical instruments for re-use. Autoclaves are also used to destroy all microorganisms that may be present in medical waste before disposal in a traditional landfill. The autoclave lowers the pressure within the chamber, which shortens the amount of time required to generate steam.

Medical waste that is subjected to an autoclave is often also subjected to a compaction process, such as shredding (after treatment), so that it is no longer recognizable and cannot be re-used for other purposes. The compaction process reduces the volume of the treated waste significantly. After treatment and compaction, the treated waste can be combined with general waste and disposed of in traditional manners. Waste that is treated using an autoclave is still recognizable after treatment, and therefore must be shredded after treatment to allow for disposal with general waste. Autoclaves are not recommended for the treatment of pathological waste, due to the recognizability factor after treatment, and that specific infectious waste may contain low levels of radioactive material or cytotoxic compounds. The autoclave process can aerosolize chemicals present in the waste and depending on the design of the autoclave; these chemicals can be released into the air when the autoclave is opened.

Autoclaves can be used to process up to 90% of medical waste, and are easily scaled to meet the needs of any medical organization. Small counter-top autoclaves are often used for sterilizing reusable medical instruments. Large autoclaves are used to treat large volumes of medical waste at once.

## Steam sterilization provides a methodology to treat waste in a cost-efficient manner. The destruction of the microorganisms is highly effective, but the problem comes when transportation is required. Many landfills and general incineration facilities are reluctant to accept the waste, fearing the waste is infectious.Mechanical/Chemical Disinfection

Chemical disinfection, primarily through the use of chlorine products, is another method used to treat medical waste. The use of chlorine bleach for cleaning and disinfecting is well known and this method has been in use for many years. The mechanical/chemical disinfection process provides control and consistency to the disinfection process. The EPA identifies chemical disinfection as the most appropriate method to treat liquid medical waste. Chemical disinfection processes are often combined with a mechanical process, such as shredding or maceration, to ensure sufficient exposure of the chemicals to all portions of the waste. The disinfectant is usually combined with a large amount of water to assist with the disinfection process and to cool the mechanical equipment in the shredding process. Liquid waste treated with a mechanical/chemical disinfection process can usually be discharged into the sewer system, as long as the organization has obtained the proper sewer discharge permits from their city. Mechanical/chemical disinfection treatment devices are primarily on-site installations, rather than mobile treatment units, though these devices are available in different sizes, which are based on the amount of waste to be treated. Recent work in Japan has also found a method of chemically stabilizing heavy metals in fly ash from medical waste incinerators. Much development goes on in Japan, including [recent work](http://www.iop.org/EJ/abstract/1009-0630/9/6/16/) on a dual torch plasma arc furnace.

## Microwave

The use of microwaves to disinfect medical waste has only recently been introduced in the United States. Microwave treatment units can be either on-site installations or mobile treatment vehicles. In this type of disinfection process, the waste is first shredded. The shredded waste is then mixed with water and subjected to microwaves. The microwaves internally heat the waste, rather than applying heat externally, as in an autoclave. The heat generated in this method provides even heating over all portions of the waste, and the high-temperature steam that is generated effectively neutralizes all biologicals. The shredding operation reduces the volume of the waste by up to 80%, and the treated waste can be disposed of in a landfill. The entire process takes place within a single vessel, and the system can be operated by unskilled workers. Treatment of medical waste through exposure to microwaves is less expensive than incineration. This method is not recommended by the EPA for the treatment of pathological waste.

## Irradiation

Another method used to sterilize medical equipment or waste is irradiation, generally through exposure of the waste to a cobalt source. The gamma radiation generated by the cobalt source inactivates all microbes that may be present in the waste. Dedicated sites are required for this form of treatment, as opposed to the mobile versions available for other non-incineration methods. One private company that specializes in this form of treatment shreds the treated waste after irradiation, and then ships the waste to a cement kiln, where it is burned as fuel. The cost of developing a dedicated facility for this method is quite high, and therefore this method is not as widely used as other treatment methods at this time. The risk of radiation exposure by workers operating the facility, while low, is also a factor. Also, pathological waste cannot be treated using irradiation. Questions have been raised about the effectiveness of irradiation to provide consistent treatment across a batch of waste. (Due to the inconsistency and control of batch waste density, assuring effective kill of bacteria can be a challenge).

**SINGLE USE DISPOSABLE MEDICAL DEVICE IMPACT ON THE WASTE STREAM**

The multibillion dollar disposable medical device industry was spawned in the United States during the 1940s, in an effort to provide sterile products safely to hospitals and clinicians, and grew exponentially through the 1960s. Many companies continue to enjoy double digit growth in this market today, and expansion of these products has been global. This technology substantially reduced infection rates among patients, which was a leading cause of death at hospitals and healthcare facilities. The ability to package products and sterilize them at the point of manufacture were of critical importance during World War ll as soldiers were treated in the field for wounds. Prior to the creation of disposable devices, statistics clearly demonstrated that more soldiers died of infection rates rather than tissue damage resulting from the wound itself. The disposable medical device industry made further advancements over the next decade with the development of plastics and creation of many new and innovative product offerings. The disposable medical device industry continues to grow at double-digit rates each year, adding significantly to the waste stream.

In the past, medical devices used in healthcare facilities were divided into two categories:

1. **reusable devices,** items intended to be cleaned, inspected and either disinfected at a very high level, or sterilized for multiple reuses;

2. **disposable devices** intended to be used once and then discarded.

The plastics revolution, however, has permanently changed the way healthcare is delivered by providing less expensive, disposable products for a multitude of purposes and procedures. Although disposables, such as single-use needles and syringes, minimize the risk of cross-contamination, plastics inadvertently also have increased healthcare costs for waste removal and environmental pollution resulting from incineration (burning). Today more than 20 different types of plastics are used to produce hundreds of disposable medical devices, ranging in cost from a few cents (syringes) to more than a thousand dollars (electrophysiology catheters inserted into the heart to measure and correct rhythm disorders). Globally, hospitals are looking at ways to increase the reuse of disposable devices. There are many examples. Although designed for single use (disposable), US hospitals have historically reused specific types of catheters. Thus, the issue really is not whether or not to reprocess, but what constitutes safe and appropriate reuse of disposable items. This is a challenge hospitals are taking on in an effort to not only lower cost, but to effectively reduce the waste stream.

U.S. hospitals produce over three billion tons of waste each year. This volume continues to increase rapidly as hospitals struggle with a triple threat of challenges: cost containment; environmental impact; and protecting staff, patients, and the community at large from the spread of infectious diseases. Significant changes are under way in the way that hospitals manage regulated and non- regulated medical waste. In recent years, hospitals have begun to transition from the waste-to-energy (via on site incineration) practices of the past, toward technologies that disinfect waste prior to disposal in the municipal waste stream, typically via landfill and limited recycling efforts. Hospitals also have made great strides in reducing the regulated waste stream (at $600-$800 per ton) to the non-regulated waste stream ($30-$40 per ton) over the past two decades. Programs instituted at leading institutions such as Kaiser Permanente, Inova, University of Vermont Medical Center and many others are well documented. These programs resulted in significant reduction in the overall waste stream, in some instances by as much as 30%. Some of the efforts focused on:

* Improved segregation of red bag and non infectious waste. This was key to improving recycling efforts of commodity materials, particularly with plastics.
* Utilizing autoclaving technology to render potentially infectious waste, reducing volume of red bag waste in some instances by as much as 40% in certain applications.
* Pursue reusable medical product applications vs. disposable products as appropriate. On site and contract sterilization of reusable instruments is a prime example.
* Encourage medical device manufacturers to proactively pursue environmental packaging initiatives with a focus on reduction in material, recyclability and reusability where applicable. The use of objective and scientific modeling is key to driving these types of programs.

Medical packaging can contribute between 30 to 50 percent (or more) to the overall medical waste stream, creating a focal point of opportunity. Major Hospital groups have begun to evaluate sustainable packaging as part of the purchasing decision process. They stand to realize huge cost benefit and improve regulatory compliance, when sustainable packaging is done correctly. One major medical device manufacturer of Urology drainage sets won several major accounts increasing revenue substantially through conversion of rigid to flexible packaging. Materials that were used demonstrated improved recyclability, reduced total packaging by more than 30 %, and realized savings that were shared throughout the supply chain. Another device manufacturer was able to demonstrate the elimination of corrugated cases with a new bulk shipping system that not only reduced materials, but improved overall quality and delivery to the end users.

**PHARMACEUTICALS: IMPACT ON MEDICAL WASTE STREAM**

The Global prescription drug market was $550 billion in the year 2006, with the total health care expenditures across the world estimated at $4.5 trillion. More than four billion prescriptions are written in the United States annually, and up to 35% of dispensed pharmaceuticals outside the hospital setting go unused, generating approximately 200 million pounds of pharmaceutical waste a year.  In hospitals, pharmaceutical waste is generally discarded down the drain or land filled, except chemotherapy agents, which are often sent to a regulated medical waste incinerator. These practices were developed at a time when knowledge was not available about the potential adverse effects of introducing waste pharmaceuticals into the environment. Proper pharmaceutical waste management is a highly complex new frontier in environmental management for healthcare facilities. A hospital pharmacy generally stocks between 2,000 and 4,000 different items, each of which must be evaluated against state and federal hazardous waste regulations. Pharmacists and nurses generally do not receive training on hazardous waste management during their academic studies and safety and environmental services managers may not be familiar with the active ingredients and formulations of pharmaceutical products.

**Pollution Problem**Pharmaceuticals, antibiotics, steroids, and similar substances can enter the water system through improper disposal—whether they are flushed directly into a sewer system not designed to remove them, or are disposed of in household solid waste, where they can leach into the soil of landfills. The federal government currently does not require any testing for pharmaceuticals in water and has not set safety limits on concentrations. However, various studies suggest that one or more of these substances can be found in up to 80% of groundwater streams (according to samplings made in 30 states by the US Geological Survey) and in the drinking water of more than 40 million Americans in 24 large metropolitan areas (as shown in a 2008 Associated Press survey).  The risks posed by pharmaceutical pollutants deposited or leaching into the water supply are uncertain and largely unknown. While the major concerns over pharmaceuticals in the water supply have centered on potential resistance to antibiotics and disruption of endocrine systems by natural and synthetic steroids, many other waste pharmaceuticals may have unknown consequences. According to the EPA, there are no known human health effects from such low-level exposures in drinking water, but many potential scenarios (one example being fetal exposure to low levels of medications that a mother would ordinarily be avoiding) suggest that exposure could cause problems.

**Federal Regulation Pharmaceutical waste** Pharmaceutical waste has been addressed at the legislative and regulatory levels in the US. The Resource Conservation and Recovery Act (RCRA) authorizes the EPA to control the management and disposal of hazardous pharmaceutical waste produced by pharmaceutical manufacturers and the health care industry. In December 2008, the EPA proposed a rule to allow handling of hazardous pharmaceuticals as Universal Waste, not as RCRA waste—a less stringent and less costly method of disposal that would not require segregating hazardous drugs from those not classified as hazardous. The intent is to reduce the cost of handling hazardous pharmaceutical waste and therefore lessen the potential for improper disposal. Hazardous drug disposal in health care, however, generates only a small portion of pharmaceutical waste potentially discarded into our sewers and landfills daily. Consumer disposal of unused medications is a much bigger dilemma. It is also one that is on the minds of environmental agencies and organizations throughout the country.

In February 2007, the White House Office of National Drug Control Policy issued the first consumer guidance for the proper disposal of prescription drugs. It encouraged consumers to use a take-back or mail-back option to dispose of their unused medications or, as a last resort, to adulterate the medication prior to trash disposal. There is, however, no requirement and little evidence to show that this is being done. The Drug Enforcement Agency has also proposed changing the Controlled Substances Act to revise some of the barriers, including strict handling and tracking methodologies, to safe disposal of controlled drugs by the consumer. These include some of the most dangerous pharmaceutical products. However, there is no federal standard on nonhazardous, non controlled pharmaceutical waste disposal.

**State Regulation**  
There are several examples of states restricting disposal of pharmaceuticals by health care professionals and consumers alike. For example, California has passed SB 996, which requires the California Department of Resources, Recycling and Recovery (the successor as of late July 2009 to the former Integrated Waste Management Board) to develop, in consultation with appropriate government agencies, criteria and procedures for model programs for the collection and proper disposal of pharmaceutical waste. As part of SB 966, the board is required to address home-generated pharmaceutical disposal. SB 966 directs the board to develop criteria and procedures for model programs that collect these unused or expired pharmaceuticals from consumers. The board is required to report to the Legislature by December 1, 2010 on its evaluation of the efficacy, safety, statewide accessibility, and cost effectiveness of participating model programs, as well as to provide recommendations for potential implementation of a statewide program and statutory changes. Provisions of SB 966 remain in effect until January 1, 2013.

**Proactive Strategies**It is obvious that no clear direction is yet established on the pharmaceutical waste problem. Take-back and mail-back programs are convenient options for disposal of most medications.  However, controlled substances currently cannot be disposed without cumbersome and costly restrictions such as requiring consumers to turn over controls directly to law enforcement. This restricts the use of take-back and mail-back programs for some of the most dangerous drugs—leaving the toilet or trash as the only options. The most effective way to address the unused pharmaceutical problem, though, is to combine practical solutions that support regulatory policy. Municipalities should closely monitor evolving federal and state environmental laws that relate to unused pharmaceutical disposal, and then develop mail-back and take-back programs at every level. Supporting these programs with comprehensive campaigns to educate communities on the dangers involved in improper disposal will also be critical in creating a cost-effective method of dealing with unused pharmaceuticals before they become a waste management crisis.

**HOSPITALS: ENVIRONMENTALLY PREFERABLE PURCHASING (EPP)**

Hospital facilities are now taking a two pronged approach to addressing the environmental and waste management crisis: Procurement Practices, and Waste Management Practices.

1. **Procurement:**  
   Proper procurement practices can help to reduce the amount of packaging, find alternative non-toxic products (latex, mercury, PVC), and reduce the use of disposable items. Objective mathematical models are now being used, particularly with regard to packaging to help determine the true life cycle impact and total cost of a given product. This process will provide part of the information required when comparing products on environmental impact, determining options with resuables vs. disposables, and total cost impact benchmark analysis. Although in it’s infancy, this is clearly a direction for the future as better assessment models continue to develop.
2. **Waste Management:**  
   Waste segregation can drastically reduce the volume and toxicity of the waste stream. It is a necessary component of recycling, and requires some training and education. Waste segregation will reduce the amount of materials incinerated, since only Pathological Wastes (tissue, body parts, body fluids) must be disposed of by incineration, according to the Centers for Disease Control guidelines, another Federal Regulatory agency with a focus on infectious disease. Medical products which are made of PVC plastic (#3) should especially be segregated and NOT incinerated because they can produce dioxin-like substances, which are endocrine disruptors and carcinogens. Disinfection via autoclave, microwave or chemical disinfection are effective technologies and will help reduce overall volume historically disposed via incineration.

As hospitals and healthcare providers grapple with waste management challenges, they will look in part to their suppliers for at least part of that solution. As a result, there is a growing management philosophy that encourages innovative approaches called EPP or environmental preferred purchasing. The decision to buy a particular product, will, in part, be based on a particular company’s ability to effectively address environmental impact of the product throughout its life cycle. From eliminating unnecessary packaging, to seeking substitutes for products containing mercury or other toxic substances, purchasing decisions can have a major impact in providing health care without harm.

**Eliminate Drain Disposal with pharmaceuticals**

In addition to private households, many hospitals currently dispose of excess material in syringes and I**V** bags by utilizing drains that feed into sewer systems. (The two largest sources of pharmaceuticals entering the sewer systems are believed to be from hospitals and households). Wastewater treatment plants are designed to remove conventional pollutants such as suspended solids and biodegradable organic material, but they are not designed to remove low concentrations of synthetic pollutants such as pharmaceuticals. The removal efficiencies of pharmaceuticals appear to be chemical-specific. Limited testing suggests that certain types of treatment substantially remove some pharmaceuticals. However, many synthetic compounds are designed to be resistant to biological degradation and there doesn’t appear to be a single wastewater treatment technology that will remove all of the pharmaceuticals. Careful consideration should be given to eliminating drain disposal of unused IVs and other drugs. States such as California and Washington have already prohibited the sewering of virtually any drugs. For states where land filling of non-hazardous drugs is legal, the landfills generally require MSDSs for each pharmaceutical that is to be land filled so they can assure themselves it is not a RCRA hazardous waste, and they are permitted to accept it. Land filling non-hazardous pharmaceutical waste should be avoided, both for environmental and security reasons. Drugs added to a land fill will eventually leach into groundwater or be deliberately sewered by the land fill from its leaching beds. Unless immediately rendered non-recoverable in some way, drugs brought to a land fill are also subject to diversion. Diversion is being evaluated from the legal context as follows: A number of Public Interest groups (PIRGs) on both the Federal and local levels are pushing for reclamation programs driven either by Pharmaceutical companies of by the government to collect unused drugs. Due to the complications with such a process, cost, effectiveness and the need to guard against criminal activity will be essential to such a program’s success.

**Use Non-PVC IV Sets**

Many pharmaceutical products are prepared and dispensed in PVC-containing IV bags and

tubing. . The use of non-PVC IV sets for all chemotherapy drugs can reduce the adverse environmental and public health impacts of treating the waste in a regulated medical incinerator. Non-PVC bags (typically employing a variety of polyolefin structures,) are a little more expensive but compared to the cost of the drug the increased expense is insignificant. In addition, polyolefins leave a primary residue of CO2 and H20 vs. more toxic residues from PVC when incinerated. To the extent possible, all pharmaceutical waste being incinerated should be administered in PVC -free IV sets.

**EXTENDED PRODUCER RESPONSIBILITY (EPG)**

A more formalized element of the hospital’s EPP program, involves the Extended Producer

Responsibility or EPR. Although this approach is relatively new and in it’s infancy in the U.S., it is taking a

foothold, and will have an overall impact in years to come. Similar programs in the EU and other parts of the globe have demonstrated various degrees of success with healthcare applications. Critical elements of this program are as follows:

* Extended producer responsibility (EPR) shifts the burden of product waste management back onto the companies that make the products that become waste.
* EPR requires companies that manufacture and/or sell products and packaging to be financially or physically responsible for such products after their useful life. Quite simply, EPR advocates believe that to get to the root cause of waste, communities need to stop picking up after the producers of products that become waste and begin demanding that they do so themselves.
* Companies, of course, may pass costs along to consumers. But when true lifecycle costs - such as the price of waste disposal or pollution clean-up - are reflected in product prices, it creates a market incentive for producers to design better products. If companies have to pay for managing products when they are used up, they have an incentive to make products that last longer, recycle easily, and don't contain toxic chemicals.
* EPR legislation has been passed in the European Union and is spreading to most industrialized countries. It is being applied to products as diverse as packaging, automobiles, electronics, batteries, paint and pharmaceuticals.
* C[lean production](http://no-burn.org/article.php?list=type&type=92), and [zero waste](http://no-burn.org/article.php?list=type&type=90) are 2 additional solutions to this approach concerning the global waste crisis.
  + Clean production is a management philosophy covering the design of manufacturing processess that reduce or eliminate the use and generation of hazardous substances.
  + Zero waste is a philosophy that encourages the redesign of [resource](http://en.wikipedia.org/wiki/Natural_resource) life cycles so that all products are [reused](http://en.wikipedia.org/wiki/Reused). Any [trash](http://en.wikipedia.org/wiki/Trash) sent to [land fills](http://en.wikipedia.org/wiki/Landfills) is minimal. The process recommended is one similar to the way that resources are reused in nature.  
    Green chemistry is innovative, smart, and ethically responsible. The most successful chemical companies of the future will be those who exploit its opportunities to their competitive advantage, and the most successful chemists of the future will be those who use green chemistry concepts in Research and Development, innovation and education.

**HEALTHCARE MANUFACTURER STRATEGIES WITH ENVIRONMENTAL IMPACT**

As Healthcare manufacturers wrestle with the development of environmental strategies, there are key elements that must be considered first in establishing Mission Statements, Corporate Strategies and Projects. ***Successful corporate sustainability programs  are supported by three pillars:*** executive buy-in from the start, creation of an effective sustainability committee, and the establishment of clear and measurable sustainability goals.

**Executive Buy-in**

Developing a successful sustainability strategy in the businesses community will be predicated on buy-in from the various levels of its executive management team. Identification of clear cost savings, brand impact, and customer requirements are critical to the environmental strategy and successful implementation of it’s programs.

**Establishing a Sustainability Committee**

Companies with successful sustainability efforts have found it useful to establish a sustainability committee that is typically made up of high-level executives and managers from multiple divisions. This diversity of expertise is necessary because sustainability affects so many different aspects of an organization. These committees take on the task of establishing the high-level sustainability focus areas or priorities and shaping the sustainability strategy.

**Outlining Sustainability Goals & Execution**

Once a company has established its sustainability priorities, it is important to identify specific activities that will be pursued and to tie these specific activities back to the high-level sustainability goals outlined by the company’s sustainability committee or team. Data produced by McKinsey Quarterly suggests that the more tightly integrated a sustainability program is into a company’s core business values, the more likely it is to have an impact on company value. The company also needs to determine what projects are worth pursuing in the near term, and which projects can be tabled for the immediate future.

After a company has decided to move forward with a sustainability plan, one of the major considerations is determining what areas will comprise the core sustainability pillars. The paper outlines three approaches:

**3Rs (reduce, reuse, recycle)**

This strategy focuses on decreasing consumption of resources, energy, and materials in the manufacturing process, diverting material from landfills by reusing or remanufacturing items, and recycling material after its initial use.

**Most Impactful:** This approach involves tackling projects that have the most impact on the environment or the bottom line, or the activities that are the easiest to execute at the present time. A list of plastics and recycling designations are as follows:

## Plastic Recycling Codes

**Polyethylene Terephthalate (PET, PETE)**. PET is clear, tough, and has good gas and moisture barrier properties. Commonly used in soft drink bottles and many injection molded consumer product containers. Other applications include strapping and both food and non-food containers. Cleaned, recycled PET flakes and pellets are in great demand for spinning fiber for carpet yarns, producing fiberfill and geo-textiles. Nickname: Polyester.



USES: Plastic trays used to package medical devices, films used in both product and flexible packaging, sometimes used with pharmaceutical applications.

Potential problems: PET/PETE degrades with use, and wrinkled surfaces can host germs--as can backwash. PET/PETE bottles can contain trace amount of Bisphenol A (BPA), a synthetic chemical that interferes with the body's natural hormonal messaging system. BPA has been linked to breast and uterine cancer, an increased risk of miscarriage, and decreased testosterone levels. his problem is amplified when the container is filled with hot liquids or exposed to high heat such as being left in a car.

**High Density Polyethylene (HDPE)**. HDPE is used to make both rigid and flexible medical packaging applications.



Potential Problems: No known problems.

**Vinyl (Polyvinyl Chloride or PVC)**: In addition to its stable physical properties, PVC has excellent chemical resistance, good weatherability, flow characteristics and stable electrical properties. The diverse slate of vinyl products can be broadly divided into rigid and flexible materials. Bottles and packaging sheet are major rigid markets, but it is also widely used in the pharmaceutical market. Blood bags, medical tubing and many other applications. Use PVC



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Potential Problems: Contains numerous toxic chemicals called adipates and phthalates ("plasticizers"), which are used to soften brittle PVC into a more flexible form. PVC is commonly used to package foods and liquids, Medical Device tubing sets and componentry, pharmaceutical rigid and flexible packaging. It is also used in plumbing and building materials, and in everything from cosmetics to shower curtains, all of which are found in Healthcare facilities. Traces of these chemicals can leach out of PVC when it comes into contact with food. Vinyl chloride (the VC in PVC), as a known human carcinogen. The European Union has banned the use of DEHP (di-2-ethylhexyl phthalate), the most widely used plasticizer in PVC.

**Low Density Polyethylene (LDPE)**.Used predominately in film applications due to its toughness, flexibility and relative transparency, making it popular for use in applications where heat sealing is necessary. LDPE is also used to manufacture some flexible lids and bottles .



**Polypropylene (PP)**. Polypropylene has good chemical resistance, is strong, and has a high melting point making it good for hot-fill liquids. PP is found in flexible and rigid packaging to fibers and large molded parts Rigid and flexible packaging used with some forms of autoclave sterilization and medicine bottles.



**Polystyrene (PS)**. Polystyrene is a versatile plastic that can be rigid or foamed. General purpose polystyrene is clear, hard and brittle. It has a relatively low melting point. Typical applications include protective packaging, containers, lids, cups, bottles and trays.



Use include aspirin bottles, rigid medical device packages and thermoformed parts.

Other. Use of this code indicates that the package in question is made with a resin other than the six listed above, or is made of more than one resin listed above, and used in a multi-layer combination. **Includes polycarbonate**.



USES: Three and five gallon reusable water bottles, some beverage containers, and medical packaging applications.

Potential Problems: Studies show polycarbonates can also leach the potentially harmful synthetic hormone Bisphenol A (BPA). This problem is amplified when the container is filled with hot liquids or exposed to high heat

**HEALTHCARE PACKAGING STRATEGIES AND ENVIRONMENTAL IMPACT**

Companies that understand and embrace sustainability will have a significant competitive advantage in the marketplace. The organizations that best understand these opportunities, will develop strategies that will maximize profits, enhance revenue and enjoy leadership roles in driving good corporate citizenship. Medical packaging plays a major role as it contributes between 30 to 50 percent (or more) to the medical waste stream, creating a focal point of opportunity. Major hospital groups have begun to evaluate sustainable packaging as part of the purchasing decision process. They stand to realize huge cost benefit, improved regulatory compliance, and enhanced CSR when sustainable packaging is done correctly. Developing a comprehensive strategy both long term, and short term is critical. Several factors will need to be addressed as follows:

1. Develop a Package Sustainability mission statement: Incorporate with company Environmental Policy. Ensure senior management buy in, and incorporate as part of the standard operating procedures in conjunctions with all new product development. Work collaboratively with other functional disciplines to support efforts across the organization.
2. Develop Legislative benchmark and compliance strategy: Fully understand existing legislative requirements in all global locations that products and packaging are sold within. Establish action plans focused on compliance. Work with the various regulatory bodies, and industry groups toward the development of sound legislative policy and position your organization to anticipate future requirements.
3. Engage Voice of the Customer; understand strengths, weaknesses, and opportunities as they relate to the challenges of Waste Management both internal to your organization and with the customers: Understand the waste management process, trends and challenges. Understanding present and future direction will provide the basis for developing effective strategies that will better meet these evolving needs. In doing so, opportunities to increase revenue, lower cost and provide the basis for good corporate citizenship will be enhanced.
4. Establish objective, industry accepted benchmark analysis focused on Life Cycle Analysis (LCA) mathematical modeling to support Sustainable modeling: In an effort to avoid “Greenwashing” and non – legitimate labeling and marketing claims, use Life Cycle Analysis models to support efforts focused on source reduction, sustainable package material selections, sustainable manufacturing processes and equipment as well as impact to the supply chain (eco footprint).
5. Maximize concepts of reuse, reduction and recycling throughout the entire LCA
6. Eliminate or change materials that create environmental deficiencies in the medical waste
   1. PVC and plasticizer replacements,
   2. Materials that are inert or non harmful with landfill, incineration, chemical disinfection, microwave waste management technologies
7. Promote success stories within the industry

**SUCCESS STORIES**

As Healthcare institutions address the development of their strategy base, it is important to understand some of the success stories that will continue to benchmark future direction and evolution of policy. Here are a few of those stories:

* Ridgeview Medical Center in Waconia, MN (2006) participated in a waste audit performed by its medical waste vendor. The vendor identified the need for and conducted appropriate training within four months. As a result of this training, the medical center succeeded in reducing regulated medical wastes by almost 30 percent in 2006, and by almost 25 percent in 2007 based upon its benchmark of 1.18 per adjusted patient day.
* Other well-documented programs instituted at Kaiser Permanente, Inova, University of Vermont Medical Center, and many other leading institutions have significantly reduced the overall waste stream, in some instances, by as much as the 30 percent achieved at Ridgeview. Some approaches used at these institutions focused on:
  + Improved segregation of red bag and non-infectious waste. This was key to increased recycling of commodity materials, particularly plastics.
  + Utilizing autoclaving technology to render potentially infectious waste safe, reducing the volume of red bag waste by as much as 40 percent in certain applications.
  + Identifying and perusing appropriate opportunities to displace disposable medical products with reusable medical products. This is often accomplished via either on-site or contract sterilization of reusable instruments.
  + Encouraging medical device manufacturers to proactively pursue environmental packaging initiatives with a focus on material reduction, recyclability, and reusability, where applicable. Scientific modeling is key to driving these types of programs.
* The materials used in this example reduced total packaging by more than thirty percent, carbon footprint by 40%, and improved recyclability to provide cost-savings across the supply chain. Another device manufacturer demonstrated that by replacing corrugated cases with a new innovative bulk shipping systems, they could reduce materials while improving overall quality and delivery to the end users.
* Other possible developments that medical product manufacturers can employ to improve the sustainability of their packaging, include eliminating paper inserts, and replacing printed instructions (IFUs) with a CD and/or web page in markets that support the regulatory compliance to do so.

## Using mathematical models to develop sustainable packaging.

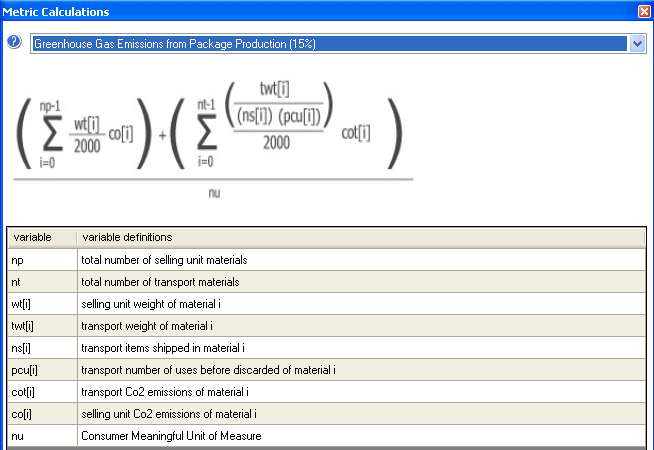
Sustainable packaging design starts at the point of manufacture. Cradle-to-grave life cycle analysis through mathematical modeling makes it possible to determine and manipulate several key metrics to provide a weighted average on total sustainability. These metrics can include carbon footprint, greenhouse gas emissions throughout the supply chain, recyclability, and cube. The weighted average, which can be visualized as a spider diagram (See Figure 1), provides a clear evaluation of a given solution (including trade assessments) on each attribute being evaluated.



FIGURE 1: Packaging model spider chart provides clear

comparison of environmental indicators.

While still in its infancy for medical product packaging applications, packaging engineers in other industries have used several different software applications with good success. The Walmart model (<http://www.scorecardmodeling.com/>) in particular, which is widely recognized in retail markets, can be adapted for medical product applications by incorporating the industry’s unique regulatory parameters use to perform a series of objective calculations. (See Figure 2) l.



Using this model, engineers can input detailed packaging information in order to make the best design decisions that will meet an objective environmental assessment that takes into account the full Life Cycle Analysis.

Several hospitals are now working with this powerful tool in an effort to objectively evaluate environmental impact of a given package as part of the purchase decision process. They also want to further explore how the tool can be used to substantiate future environmental claims to avoid potential charges of “greenwashing” from an increasingly skeptical public. Progressive device manufacturers can use this tool to benchmark their products to gain a competitive advantage in the marketplace. Medical products manufacturers and institutional consumers alike can collaborate on efforts to develop, support, and prove the effectiveness of their environmental strategies. Furthermore, as more and more countries develop regulations for both medical product safety and packaging waste reduction (such as the German Green dot legislation), the modeling tools can help health care providers and medical product manufacturers achieve and substantiate compliance.

Additional cost modeling can be performed to demonstrate cost-saving opportunities for both device manufacturers and distributors and hospitals. (See Figure 3 BELOW)

