Treatment of Biomedical Waste with Ozone

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Introduction

In 2006, the annual American Hospital Association survey on hospitals reported there were nearly 950,000 hospital beds in the U.S.[1] In Canada in 2005 the number of acute care hospital beds was approximately 103,000.[2] Combined, there are over 1 million hospital beds in Canada and the U.S. Annual waste production in hospitals is about 2 tonnes per hospital bed, or about 2,000,000 tonnes in total.[3] Of this, about 15% is considered hazardous waste, including materials such as biomedical, pharmaceutical, chemical, and laboratory wastes.[4] In addition, there are about 500,000 private clinics, not reflected in the statistics cited above.[5] As a result, the amount of biomedical waste produce in North America each year is significant.

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[1] American Hospital Association 2006 Survey – http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html.

[2] Based on 3.2 beds per 1,000 population as reported in *OECD Health Data 2005: How does Canada Compare* – http://www.oecd.org/dataoecd/16/9/34969633.pdf; Population of Canada in 2005 was estimated to be 32,312,077 according to Statistics Canada – http://www.statcan.ca/english/freepub/98-187-XIE/pop.htm#table3.

[3] *P2 Fact Sheet – Pollution Prevention in the Health Sector* – http://www.ec.gc.ca/nopp/docs/fact/en/health.cfm; Rutala *et al*., *Medical Waste: SHEA Position Paper*, Infection Control and Hospital Epidemiology, January 1992, pp.38-28 – http://www.shea-online.org/Assets/files/position_papers/Med-Waste92.PDF.

[4] Rutala et al. (1989). *Management of Infectious Waste by Hospitals*. JAMA, 262: 1635-1640.

[5] U.S. Environmental Protection Agency. *Medical Waste Management in the United States: First Interim Report to Congress*. EPA/530-SW-90-051A; 1990.

Conceptually, there are essentially two ways in which to deal with biomedical and other hazardous wastes. One is through segregation. Hazardous wastes can be separated from non-hazardous materials, and then placed in designated containers designed to prevent release into the environment. The second is by waste treatment, where the wastes are treated in some way to render them non-hazardous.

There are significant problems with segregation type waste management. These include finding acceptable locations for the containers, as well as designing containers that will not permit release of the waste for extended periods of time. The challenges faced by the nuclear power industry with respect to the removal and storage of spent nuclear fuel is a primary example of the difficulties that arise when segregation type waste management is used.

There is a similar public concern over biomedical waste, particularly in view of several well-publicized cases in the 1980's where biomedical waste was found to have washed up on public beaches. Because of the concern over AIDS and other infectious disease, the public perceives that the unregulated handling of biomedical waste poses a serious threat to health and safety.[6] In 2004 the World Health Organization (WHO) released a policy paper on the subject of biomedical waste underscoring the risk of infection by exposure to biomedical waste, especially in areas where needles and syringe are scavenged from waste areas and dump sites. For example, the WHO estimated that in 2000, worldwide there were 21 million hepatitis B virus (HBV) infections, 2 million hepatitis C virus (HCV) infections, and 260,000 HIV infections due to injections with

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[6] Burdick, A. *Hype tide*. The New Republic, June 12, 1989; pp.. 15-18.

contaminated syringes.[7] The WHO also states that the chance of infection from one needle-stick from a needle used on an infected source patient is 30% for HBV, 1.8% for HCV, and 0.3% for HIV.

Since that the proportion of waste that has actually come in contact with an infected patient is a small fraction of total biomedical waste, the overall risk of random infection will of course be lower than the risks of infection reported by the WHO cited above. However, despite the low risk, and because of the current trend in society towards "zero risk", these occurrences and the public perception of risk they created, has led to the passage of biomedical waste regulations by a number of states in the U.S. and similar legislation in Canada. The handling and management of biomedical and other hazardous wastes is under ever-increasing regulation and scrutiny, which has in turn led to a significant increase in the cost of handling biomedical waste.[8] As a result, there is a need to develop waste management technologies that meet the standards imposed by government regulations, but which do so at an economically sustainable cost. In addition, any waste management system should be as "environmentally friendly" as possible, given emerging trends and policies with respect to energy use and the potential for environmental contamination, especially ground water.

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[7] *Safe health-care waste manangement*, World Health Organization Policy Paper, August 2004; http://www.who.int/water_sanitation_health/medicalwaste/en/hcwmpolicye.pdf

[8] The cost of regulated medical waste in a New York university hospital went from $1.04 to $5.19 per patient per day; Marchese, J.T. et al., (1990). Regulated Medical Waste Disposal at a University Hospital: Future Implications. Third International Conference on Nosocomial Infections, July 31-August 2, 1990, Atlanta, GA.

One problem that has arisen in the area of biomedical waste management is the improper characterization of some waste as regulated waste in order to ensure compliance with regulations. Some savings can be made through training of health care workers in order to reduce the amount of material that is improperly placed in the biomedical waste stream. In another example, Toronto's Hospital for Sick Children reported a 35% reduction of hazardous waste resulted in a 50% savings in overall waste management costs.[9] Therefore, even small improvements in biomedical waste management can yield significant economic benefits.

However, there will always be an unavoidable amount of waste that is legitimately biomedical waste and which must be treated in order to meet local, regional, or national standards with respect to handling of potentially hazardous materials. As a result, there remains a strong demand for viable solutions to the management of potentially infectious biomedical waste.

Approaches to Treatment of Biomedical Waste

In general, the approach in North American health care facilities has been either to incinerate waste, encapsulate it, or to treat it such that it is safe for transport and placement in landfills. While incineration is effective, it is energy and thus cost-intensive, and can lead to the production of toxic by-products (e.g., fly ash, metals) that are released into the atmosphere. In addition, there is a general "not in my backyard" attitude among the public towards incineration facilities. Similarly, encapsulation is

[9] Toronto Hospital for Sick Children.

expensive both in terms of equipment needed for containing waste, and the space needed for storage. In addition, encapsulation technologies do not necessarily inactivate the waste, such that the risk of biological or chemical contamination remains should the containment system be compromised.

Thus, the most favored solution to the handling is to process such wastes so that they can be safely placed in sanitary landfills. However, two fundamental problems must be addressed in any waste management process that ultimately results in material ending up in landfill facilities. First, to meet regulatory standards the material must be made biologically safe. That means that any pathogens or other infectious agents must be effectively inactivate. Pathogenic agents commonly include bacteria, viruses, fungi, and proteinacious infectious agents (termed prions).

Secondly, the waste must be made chemically safe. This means either degrading or otherwise in activating chemical components of the material, typically pharmaceuticals, hormones, and chemotherapy drugs. Removal of drugs in waste destined for landfills is of particular concern as it has been shown that these compounds make their way into the water table, and thus create a potential for comprising fresh water supplies destined for human or animal consumption.[10]

Existing Technologies

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[10] Jasim, S.Y. et al., (2006). *Presence of Pharmaceuticals and Pesticides in Detroit River Water and the Effect of Ozone on Removal*. Ozone: Science and Engineering, 28: 415-423; Ikehata, K., et al., (2006). *Degradation of Aqueous Pharmaceuticals by Ozonation and Advanced Oxidation Processes: A Review*. Ozone: Science and Engineering, 28: 353-414; Drury, D.D., et al. (2007). *Investigating Ozone*. Water Environment and Technology, May 2007: 56-60.

As suggested above, there are a number of methods that can be used to treat waste in order to inactivate potentially hazardous pathogens and chemicals pathogens.

Incineration

In general, incinerators use very high temperatures (1800°F and above) to combust waste products.[11] All biological compounds are completely destroyed at these temperatures, and so incineration is very effective at inactivating pathogenic agents. The primary disadvantages inherent in the use of incinerators are the cost due to the energy intensive nature of the process, and the potential for release of toxic compounds in to the atmosphere, which in the past included dioxins and furans.[12]

Non-Incineration Methods

In these processes, various methods of heating without combustion are used to inactivate biological compounds. These methods include steam sterilization (autoclaving), microwave, dry heat, and macrowave processes. Other methods include the use of gamma-irradiation to inactivate biological pathogens that may be present in the waste. As with incineration, these processes can either be relatively energy intensive (e.g., autoclaving, microwaves, heating) or potentially involve handling of dangerous energy sources (gamma irradiation devices). In addition, these processes are time-consuming and as a result more costly to perform. In addition, the use of steam, heat, or

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[11] http://www.etc.org/technologicalandenvironmentalissues/treatmenttechnologies/incineration/

[12] Thornton, J. et al., (1996). *Dioxin and Medical Waste Incinerators*. Public Health Reports, 111: 299-313.

radio wave energy poses an additional occupational risk to workers involved in handling and treating the waste materials.

In addition to non-incineration methods that use various forms of energy to heat waste, chemical treatment is also used as a method for treating biomedical wastes. For example, compounds such as chlorine and various chlorine derivatives, or ethylene oxide, can be used as effective ways in which to disinfect materials. However, chemical treatment methods generally require significant contact time in order to inactivate pathogens. In addition, the use of chemicals can create their own hazardous material problem in that the disinfectant may be dangerous to handle and/or difficult to dispose of safely.

Ozone[13]

Ozone is a form of oxygen, consisting of three oxygen molecules (O_3). Unlike diatomic oxygen (O_2; the breathable oxygen present in the atmosphere), ozone is very unstable, and decays to O_2 within about 30 minutes under normal atmospheric conditions. Ozone is a powerful oxidizing agent. It is able to oxidize a number of molecules including metals (with the exception of gold, platinum, and iridium), nitrogen oxides, carbon, ammonia, and sulfides to name a few. Ozone is of particular value as a disinfectant, as it is able to promote the oxidation of carbon-carbon double bonds (C=C). This type of bond is found in many biological molecules, and in other types of organic compounds, most notably pharmaceuticals. As a result, ozone is effective to kill

[13] See: http://en.wikipedia.org/wiki/Ozone

essentially all pathogens including bacteria, fungi, viruses, as well as prions.[14] Ozone is also effective to promote the degradation of a large number of drug compounds.[15]

The generation and handling of ozone is relatively simple using a variety of available technologies that make use of oxygen in the ambient atmosphere. As a result, ozone is conveniently generated on site, and does not require specialized containers for transport, as are required with other chemicals. Further, ozone degrades naturally into oxygen in a relatively short period of time (10-30 min), and thus does not leave any toxic residue behind.

Use of Ozone as a Disinfectant

The use of ozone has been widely investigated for use in water treatment as well as for the treatment of biomedical waste. The Clark County (Nevada) Water Reclamation District recently reported the results of their own studies suggesting that ozonation is an effective method for disinfecting drinking water.[16]

Systems using ozone to disinfect biomedical waste have been developed. The TSO3 company offers an ozone sterilizer for use in disinfecting medical instruments.[17]

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[14] Burleson, G.R., et al., (1975). *Inactivation of Viruses and Bacteria by Ozone, With and Without Sonication*. Applied Microbiology, 29: 340-344; Mari, M. et al., (2003). *Non-Conventional Methods for the Control of Post-Harvest Pear Diseases*. Applied Microbiology, 94: 761-766; Murray, B. (2006). *Rapid Inactivation of Prions by Ozone*. 106th General Meeting of the American Society for Microbiology. May 21-25, 2006. Orlando, Florida.

[15] Ikehata *et al*., (See Note 12 above).

[16] See Drury *et al*., (See Note 12 above).

[17] http://www.tso3.com/en/img/video.swf

While the unit is compact, it is not designed to use in treating mixed biomedical waste. In particular, the TSO3 system does not have the ability to shred materials prior to ozone treatment, and thus is only effective for topical sterilization.

Ozonator™ System for Biomedical Waste Management

More recently, Ozonator Industries has developed an ozone treatment system specifically designed for high-throughput treatment of biomedical wastes. The Ozonator™ system combines a shredding step to reduce the waste to smaller particles (less than 30 mm), and then treats the shredded material with ozone. The design of the Ozonator™ system effectively provides a continuous batch process, with each batch taking about 10 minutes to process. Current models of the system allow for a maximum 200 kg (440 lbs) load per cycle. Shredding provides an additional advantage in reducing the volume of the waste up to 90% and increases the overall the cost-effectiveness of the system in reducing landfill costs.

Ozone is generated on-site using source water and either ambient atmospheric oxygen, or medical oxygen supply commonly available in health care facilities. The power consumption of present units is 37kW (peak). At commercial power costs of $0.10 per kWh, the cost of energy for the system is about $90 per day.[18]

The entire process, from loading, through shredding, ozone treatment, and unloading, is fully automated, reducing the exposure of workers to materials. The system also has a variety of safety features to ensure shutdown should any part of the process fail

[18] Based on average U.S. Commercial Electrical Power rates as of May 2008; http://www.eia.doe.gov/cneaf/electricity/epm/table5_6_a.html

to operate within defined parameters. The system is also easy to train on, and workers can be fully trained in its operation in about an hour.

Once materials are loaded into the system, ozone begins to flood the chamber. When ozone levels reach 1000 ppm shredding begins. During the treatment phase, ozone levels are maintained at a level of at least 3500-4500 ppm.[19, 20]

Efficacy Testing

To test the effectiveness of the Ozonator™ system, three different assays have been used. In the first set of experiments, a total of 20 STS Spore strips, each strip containing 6 x 10^5 *Bacillus atrophaeus*, and 1 x 10^5 *Geobacillus stearothermophilus* spores respectively, were treated with ozone for one hour.[21] After ozone exposure, strips were sent to an independent laboratory to be tested for spore viability.[22] Spores were germinated at 35°C and 55°C in liquid culture and on agar plates. The results showed at least a 10^4-fold reduction in spore viability, and 39/40 strips were negative for growth (no viable spores) after treatment in the Ozonator™ system.

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[19] Typically ozone levels of 10-50 ppm are effective to kill bacteria in water environments.

See http://www.edstrom.com/Resources.cfm?doc_id=149

[20] Ozone levels are monitored in the post-treatment chamber in the airspace above the treated material. Since ozone has a density greater than air, it is expected that ozone levels in the treated material are greater than that in the airspace, and as a result, actual ozone concentration in the treated material is likely greater than the measured value. In addition, ozone has a half-life of about 30 minutes under ambient atmospheric conditions. Since after material is moved to the post-treatment chamber, no additional ozone is actively added, the ozone present after treatment begins to naturally decay. Therefore, the residual ozone in the post-treatment chamber is likely lower than the levels attained during the material treatment phase of the process. As a result, the levels of ozone as measured likely represent less than actual ozone levels during treatment, and therefore can likely be considered minimum levels attained.

[21] STS Spore strips are compliant with ANSI/AAMI/ISO/EN 11138 series of standards, and USP where applicable.

[22] BDS Laboratories, Qu'Appelle, SK

In a second method, 3M Attest™1294 Biological indicators were used to test bacterial spore viability after ozone treatment. 3M Attest™1294 indicators contain a standardized population of viable *Bacillus subtilus* ATCC 9372 spores. The results of these tests showed at least a 10^6-fold reduction in spore viability after treatment with the Ozonator™ using standard treatment protocols.

Finally, within each batch the Ozonator™ system has the ability to include an FDA-cleared, ozone-specific colorimetric indicator to confirm that ozone levels have reached a pre-determined minimum level.[23]

The output from the Ozonator™ system is sterile waste that is landfill-ready. Testing of material processed using the Ozonator™ shows that at least 99.9999% of microorganisms are killed by the ozone treatment process (a 1 million-fold reduction in pathogen levels).[24] After processing, waste is discharged into a disposal tank, which is then suitable for removal to a landfill site.

The Ozonator™ has been recently approved by the North Carolina Department of Environment and Natural Resources for use in treating regulated medical waste, including microbiological and pathological wastes.[25] Approval in California is currently pending.

Summary

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[23] http://www.tso3.com/en/products-services/accessories.php

[24] Using 1294 ATTEST™ Biological Indicators; available from the 3M Company.

[25] As of January 2, 2007.

Taken together, the features of the Ozonator™ provide for an energy-efficient, environmentally friendly, and cost-effective[26] alternative to traditional biomedical waste treatment methods.

[26] Union Hospital in Terre Haute, Indiana reports a 40% reduction in waste handling costs in the first months of operations of an Ozonator™ waste processing system.