Alternative to Incineration of Biomedical Waste: Autoclaving

A report for the

Commonwealth of Dominica

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Preface

The "burning" or "incineration" of waste is an age-old practice that continues in the world today. Advances have been made in the design and operation of "incinerators" to greatly reduce their impact on the environment as well as public health. The impact of years of poor disposal practices and improperly operated incinerators are still being assessed in certain areas and yet to be determined in others. Given the appropriate expenditures on air pollution control equipment and operations, incineration remains a standard method of waste disposal primarily because its greatest benefit is volume reduction. Dominica is now considering an updated approach to biomedical disposal – incineration or an alternative approach.

However, one must consider the following issues and compare them to the alternatives:

Excerpted from "Non-Incineration Medical Waste Technologies" – Health Care Without Harm, August 2001 www.noharm.org

INCINERATORS EMIT TOXICAI R POLLUTANTS

A medical waste incinerator releases into the air a wide variety of pollutants including dioxins and furans, metals (such as lead, mercury, and cadmium), particulate matter, acid gases (hydrogen chloride and sulfur dioxide), carbon monoxide, and nitrogen oxides. These emissions have serious adverse consequences on worker safety, public health and the environment. Dioxins, for example, have been linked to cancer, immune system disorders, diabetes, birth defects, and other health effects. Medical waste incinerators are a leading source of dioxins and mercury in the environment. It must be noted, however, that non-incineration technologies can also have toxic emissions (although research indicates that these occur in smaller amounts).

INCINERATOR ASH IS POTENTIALLY HAZARDOUS

Ash remaining at the bottom of an incinerator after burn down often contains heavy metals that may leach out. Dioxins and furans may also be found in the bottom ash. In states where low-level radioactive waste is incinerated, the ash residue may also contain traces of radioactive isotopes. If test results of the ash exceed the limits under EPA's toxicity characteristic leachate procedure (TCLP), the ash must be treated as hazardous waste. TCLP is a testing procedure wherein an extract from a 100 gram sample of the ash is tested for 40 toxic sub-stances; if the analysis shows that one of the substances is present at a concentration higher than that specified in the regulation, the ash is considered hazardous waste. Disposal of hazardous waste is subject to regulations under the Resource Conservation and Recovery Act (RCRA). Note, however, that the TCLP tests for only a limited number of toxic substances and is conducted on a very small sample that may not be representative of the entire batch of bottom ash. TCLP uses an extraction procedure that does not reproduce long-term natural leaching as occurs in landfills. Moreover, not every batch of ash is tested. Due to the diverse materials that comprise medical waste, the resulting ash composition will vary considerably and yet some facilities test the ash only once a year or only one time.

Fly ash (ash that is carried by the air and exhaust gases up the incinerator stack) contains heavy metals, dioxins, furans, and other toxic chemicals that condense on the surface of the ash. Even when the fly ash is removed from the exhaust stream by pollution control devices such as baghouse filters, the toxic materials remain concentrated on the filter cake and should be treated as hazardous waste.

INCINERATORS MUST MEET "NEW" REGULATORY REQUIREMENTS

New and existing medical waste incinerators must comply with the 1997 EPA regulation that sets limits on their air emissions. To meet the requirements, incinerators will need air pollution control devices such as scrubbers.

In older incinerators, secondary chambers may have to be retrofitted. Periodic stack tests must be performed to show compliance with the rules, and facilities must continuously monitor operating parameters such as secondary chamber temperature. The regulations also require operator training and qualification, inspection, waste management plans, reporting, and recordkeeping.

Before 1997, there were no federal regulations governing air emissions from medical waste incinerators. Under the regulation, operators of medical waste incinerators must meet the emission limits within a year after the EPA approval of their state's implementation plan or, if their states do not have their own control plans, in keeping with the federal implementation plan promulgated in August 2000. Regardless of which plan applies to a specific incinerator, all existing medical waste incinerators must be in full compliance by September 2002. (More information about the "hospital/medical/infectious waste incinerator rule" can be found in http://www.epa.gov/ ttnuatw1/129/hmiwi/rihmiwi.html; see also Chapter 10.)

INCINERATORS MAY NOT BE COST-EFFECTIVE

Cost is another key factor in the consideration of medical waste disposal. In evaluating the costs of incineration,
decision-makers should take into account, among others, capital and operating costs of the incinerator plus scrubber and other pollution control devices; the cost of secondary chamber retrofits for old incinerators; the costs of periodic stack testing, continuous monitoring, operator training and qualification; and the costs of maintenance and repair especially in relation to refractory wear or failure. The hospital mentioned earlier estimated that installing the necessary pollution control devices on their incinerator to meet the EPA rule would add $650,000 more in costs than a recycling option.

MANY COMMUNITIES OPPOSE INCINERATION

A plume of smoke from a hospital incinerator stack stands as a frequent reminder of that facility's environmental impact on the surrounding community. The public's concern for a clean environment and increasing community opposition to incineration should be paramount factors in deciding whether or not to install or continue operating a medical waste incinerator. Choosing a cleaner non-incineration technology demonstrates the health care organization's commitment to protecting public health and the environment.

No technology offers a panacea to the problem of medical waste disposal.

In general, however, non-incineration technologies appear to emit fewer pollutants. Most non-incineration technologies generate solid residues that are not hazardous. Alternative technologies (in particular, non-burn technologies) are not subject to EPA's medical waste incinerator regulations. Many hospitals have also concluded that upgrading or purchasing an incinerator is not as cost-effective as implementing a waste minimisation program and installing a non-incineration technology.

Alternative To Incineration of Biomedical Waste

Autoclaving

Introduction

This report is being generated for the Common Wealth of Dominica to provide guidance in the area of alternative treatment technologies for biomedical waste management, specifically steam sterilizers or autoclaves as compared to incineration. There is growing interest in alternative technologies for treatment of biomedical waste due to concerns of air pollution from biomedical waste incinerators. However, the quantities of biomedical waste generated on Dominica to not appear to be great. While many alternative technologies are available, we believe it will prove to be advantageous to Dominica, from an economic and historical perspective, to compare and contrast incineration with autoclaving.

The report is divided into the following areas:

- Technical information on the principle of steam autoclaving
- Studies on the level of microbial inactivation achieved by steam autoclaving of biomedical waste
- Qualitative comparison of the treatment of biomedical waste by incineration and by steam autoclaving
- Issue of residue disposal (e.g.. suitability of autoclave waste for landfills);
- Use of autoclaving in the USA and other countries;
- Applicable operating standards
- Waste exclusions and/or limitations (e.g.. viability of using autoclave for human tissues);
- System capacities/Economical data/information

This information is gathered from numerous studies, guidance documents, and publications listed in the reference section of this document.

I. Technical information on the principle of steam autoclaving

Background

Steam, autoclaving combines moisture, heat, and pressure to inactivate microorganisms. This process has been used for sterilizing medical instruments in hospitals for many years and the validation of autoclaving as a sterilization technique for medical equipment and supplies is well documented. Test protocols exist for evaluating this application. Steam autoclaving technology also has been used for a long time to treat biomedical waste. Medical waste may contain many of the same pathogens that are associated with contaminated medical instruments and supplies; however, biomedical waste probably contains higher levels of organisms in a more complex matrix. These differences make it necessary to develop a unique test method specifically for the assessment of steam autoclaving as an effective biomedical waste treatment technique.

R. L. Oddette (1988) reported in "Survey of Infectious Waste Management Practices in Selected Acute Care Hospitals in the United States' that 49 percent of the hospitals responding to the survey use steam autoclaving for rendering waste noninfectious before discarding. Of these 96 percent conduct some type of biological monitoring on a regular basis. Fifteen percent of these hospitals operate their autoclaves for 15 minutes; 47 percent operate it for between 15 and 30 minutes; 12 percent operate it for between 30 and 45 minutes; 17 percent operate it for between 45 minutes and one hour; and nine percent for more than one hour. Ninety-eight percent of the hospitals that operate a steam autoclave use temperature settings greater than or equal to 121^{o}C. Eighteen percent of hospitals responding to the survey incinerate their waste or send it to a sanitary landfill after steam autoclave treatment.

Most autoclave treatment processes encapsulate waste in shrunken plastic autoclave bags. Newer autoclave systems rotate or tumble wastes during treatment to enable better steam penetration and to make the wastes unrecognizable as well as reducing its volume. Autoclaving is a proven technology that is accepted by all 50 states as a method of treating medical waste. Their wide acceptance and extensive market share make autoclaves the technology to which all other biomedical waste treatment systems are

compared. Autoclaves have been available in varying sizes to treat from 10 pounds to 1,000 pounds/hour or more of biomedical waste.

General Advantages and Disadvantages of Autoclaving

Advantages:

- Can treat most types of biomedical waste
- High level of microbial inactivation of biomedical waste (See STAATT Report)
- Does not create hazardous combustion by-products (dioxin, furans, etc.)
- Produces far fewer emissions than incinerators
- Treated wastes can be landfilled along with normal municipal solid waste
- Autoclaves are the most widely used alternative to incineration of biomedical waste
- Autoclaves have extensive field/historical experience in the medical industry
- Autoclaves are widely accepted in the entire United States, Canada, several European and Pacific Rim nations.
- Autoclave is the technology to which all other alternative technologies are compared
- Many autoclaves require low capital investment

Disadvantages:

- Most autoclaves do not handle recognizable anatomical wastes[a]
- Do not handle chemotherapeutic[b] or other toxic chemical and radiological wastes
- Large volumes of liquids in sealed containers may not be adequately treated
- Offensive odors can be generated
- May exhaust volatile organic compounds (VOCs)
- May require hospital to alter method of separating waste
- Heat recovery is generally not available

[a] Two systems have been validated to treat pathological waste

[b] Hazardous chemotherapeutic waste as compared to trace contaminated materials

Steam Autoclaves: Gravity versus Prevacuum

All autoclaves are constructed with a metal chamber to withstand the increased pressure/temperature required to insure destruction of bacteria, viruses, and bacterial spores. Autoclaves come in two basic varieties, gravity displacement autoclaves and prevacuum autoclaves. The size of the device may vary from benchtop models designed to hold a single bag of waste to large commercial devices that can treat more than a ton of waste per cycle. Any test method developed for assessing the efficacy of treating biomedical waste in a steam autoclave should be applicable to all types and sizes of autoclaves that may be used as waste treatment devices.

Gravity Displacement Autoclave

The gravity displacement autoclave relies on gravity for the exchange of cool heavy air for steam. The steam enters at the top of the device and gradually replaces the existing cooler air as it moves toward the outlet at the bottom of the chamber. The efficiency of the system depends on the method of packing and loading of the waste into the autoclave to prevent the formation of air pockets where the existing air may not be displaced by steam. The operating temperature of the gravity displacement autoclave may be lower than that in prevacuum autoclaves and steam penetration may be less complete.

Prevacuum Autoclave

Prevacuum autoclaves remove air from the treatment chamber creating a high vacuum prior to the introduction of steam. This procedure allows the autoclave to reach operating temperatures more rapidly and allows the steam to penetrate the entire load more completely by reducing the chances for air pockets within the waste load. Commercially available prevacuum autoclaves used for biomedical waste treatment are devices designed to operate at 132^{o}C.

Steam Autoclaves: Type/Size

Benchtop Autoclave

A benchtop autoclave is a small steel-body electric device with self-generating steam. Benchtop autoclaves are small (16 in x 17 in x 20 in) and may be only large enough to hold only a single bag of waste each treatment cycle. Prior to each use cycle, water must be added for steam generation. The controls on the autoclave are then set for the desired temperature and duration of the treatment cycle. Benchtop autoclaves are applicable for waste treatment by laboratories or clinics (dental, medical, or veterinary) that generate only small quantities of potentially infectious waste each day. If managed properly, the benchtop autoclave may serve the dual purposes of sterilizing medical supplies for use or reuse and treating potentially infectious waste.

Benchtop, autoclaves normally have a temperature range of 100 to 132^{o}C and automatic cycle timer ranges of 0 to 30 minutes or 0 to 60 minutes. Temperature and pressure gauges provide confirmation that the treatment conditions selected are achieved in the chamber. The manufacturers usually recommend this type of autoclave be operated at 121^{o}C and 15 pounds per square inch (psi) for cycles of 15 to 60 minutes.

Laboratory Autoclave

Standard laboratory autoclaves vary in size from the size of the benchtop autoclave to more than twice that size (51 x 51 x 97 inches). They are similar in operation to the benchtop model except that they are equipped for direct connection to central steam lines.

Standard laboratory autoclaves may be used for waste treatment by larger laboratories or clinics (dental, medical, or veterinary) that generate moderate quantities of potentially infectious biomedical waste each day. The laboratory autoclave device may serve the dual purposes of sterilizing medical supplies for use or reuse and treating infectious waste. If these units are used for both purposes, care should be taken to prevent cross contamination of media, instruments and equipment.

Standard laboratory autoclaves have a temperature range of 100 to 132^{o}C. They are prepared for direct connection to steam lines with a pressure of 50 to 70 psi. The cycle timer may be set for cycles of 0 to 99 minutes.

Prevacuum - Onsite Autoclave System

Prevacuum autoclave systems are larger devices than the first two types of autoclaves described in this document. They are freestanding devices that may be installed outdoors. They are fully jacketed and are connected to direct steam lines. The chamber of the prevacuum autoclave is evacuated to a negative pressure prior to the addition of steam. Treatment temperatures in prevacuum autoclaves may reach - 135^{o}C and pressures reaching 35 psi. Treatment cycles may vary from 30 to 55 minutes. Prevacuum autoclave waste treatment systems come in a variety of sizes and are meant for use in facilities from the size of clinics and small hospitals to large hospitals of up to 800 beds.

Large Volume Offsite Gravity Displacement or Vacuum Type Autoclave Systems

The commercial gravity displacement autoclave system is a very large device. It has an onsite steam-generating boiler. This treatment system is so large it is applicable only for offsite commercial facilities. The steam is admitted to the treatment chamber through a valve in the top of the device until the pressure in the device reaches 85 psi and the temperature exceeds 160^{o}C. Each cycle lasts approximately I hour from start to finish. Because this is an offsite treatment process all types and sizes of generating facilities may use it.

II. Studies on the level of disinfection achieved by steam autoclaving of clinical waste

Several studies appear in the literature on the effectiveness of steam autoclave treatment of biomedical waste. They include the following:

Rutala et al. (1982)

Rutala et al. (1982) reported on operating parameters that sterilization of microbiological waste. Standardized test loads of contaminated petri dishes and a biological indicator containing spores of *Bacillus stearothermophilus* were packaged and placed in a gravity displacement autoclave. The biological monitoring ampoules used were Kilit (BBL Microbiology Systems, Cockeysville, Md.) standardized so that spores survive when autoclaved for five minutes at 121°C and spores are killed when autoclaved for 15 minutes at 121°C. Waste loads of five, 10, and 15 pounds of contaminated 100 mm petri plates and biological monitoring ampoules were placed in commercially available plastic autoclave bags constructed of 1.5 mil polyethylene. Bags were tested in two modes: 1) in the open position, with the sides of the bag folded down to expose the top layer of petri plates, and 2) with the opening In the bag loosely constricted with a twist-tie and four holes punched in the top of the bag. Water (500 ml) was added to some of the closed bags that were placed either in a shallow stainless steel tray or a shallow polypropylene container. The containers were placed in the steam autoclave and treated for periods of 15, 30, 45, or 90 minutes. The load temperature was monitored by thermocouple at five-minute intervals during the test. At the conclusion of the test cycle the biological indicators were removed and incubated at 56°C for seven days. Sterile swabs were dipped into the molten agar and swabbed onto blood agar plates which were incubated aerobically at 35°C for 48 hours before growth evaluation. In 10 percent of the experiments, plates were also incubated anaerobically at 35°C for 96 hours.

The study showed that the most Important factor with regard to treatment effectiveness were the types of containers holding the waste. The stainless steel container enhanced heat transfer and the open bag allowed better steam penetration than the constricted bag. The addition of 500-ml water to the closed bag did not improve the heat up time in either container significantly. As expected, the smallest loads

(five pounds) heated up faster than the larger loads. No significant difference was found in results between the 10 and 15 pound loads.

The data for the 10 and 15 pound loads indicated that 90 minutes in the stainless steel container were required to inactivate the biological indicator spores. The biological indicators were viable at all test conditions in the polypropylene container. All spore-forming and vegetative bacteria in the test loads (with or without water) demonstrated no growth after 45 minutes in stainless steel containers and after 60 minutes in polypropylene containers (without water). The test results demonstrated that for 10 to 15 pounds of waste placed in the autoclave the only conditions which insured complete kill of *B. stearothermophilus* and thus sterility of the load, were the use of a stainless steel container for treatment duration of 90 minutes.

Lauer et al. (1982)

Lauer et al. (1982) evaluated the addition of water to improve the treatment of biomedical waste loads in a gravity displacement steam autoclave. Test waste loads of 1,750 or 3,500 grams of petri dishes containing agar were placed in a polypropylene autoclavable waste bag with or without the addition of water. The specific amounts of water added to the waste loads were either 100 or 1,000 ml. Biological indicators (Minnesota Mining and Manufacturing, Inc. Attest No. 1242, *B. stearothermophilus* in a steam penetrable package simulating a linen pack) and chemical Indicators (Biomedical Sciences, Inc., Thermalog S) were also added to the waste loads. The autoclave bag containing the waste load was in turn placed in either a stainless steel or polypropylene container. The waste loads were processed for 50 minutes in the autoclave at
121^{o}C.

This evaluation demonstrated that a processing time of 50 minutes was adequate for killing all biological indicator spores and converting the chemical indicator strip in the autoclave bag containing 1,000 ml of water that was placed in the stainless steel container. All other test conditions were inadequate to kill all spores.

Glick et al. (1961)

Glick et al. (1961) evaluated steam autoclaving for the decontamination of nesting type animal cages, animal carcasses, and laboratory equipment.

A series of experiments were conducted on six stacked cages standing vertically or lying on their sides. Biological indicator organisms dried on filter paper discs (*Bacillus subtilis* var.- niger, 1 x 164 spores/disc) were placed in the litter of the used cages. Thermocouples were also placed in the litter to record the temperature in the waste load during the treatment cycle. The results of the first experiment showed that when the cages were stacked vertically and autoclaved at 15 psi, 250^{o}F, indicator organisms remained viable after four hours. When the cages were placed in a horizontal orientation and autoclaved at 20 psi, 260^{o}F, a treatment cycle of 30 minutes was sufficient to kill all indicator organisms.

The second experiment tested the ability of autoclave treatment to treat animal carcasses. Twenty guinea pig carcasses were placed in a five-gallon fiberboard container. A "Diack" sterilizer temperature indicator was inserted in the abdomen of the animal in the center of the load. The load was treated in the autoclave at 250^{o}F for time periods from one to 16 hours. It took over eight hours for the center of the load to reach the desired temperature and the controls melted before 16 hours of treatment was completed. These results indicate that the autoclave is not appropriate for the decontamination of animal carcasses.

The third experiment tested the steam autoclave for the treatment of metal equipment or equipment parts. The equipment parts were contaminated with a liquid spore suspension (B. *subtilis* var. niger, 1 x 10^{9} spores/ml) and then autoclaved both reassembled and disassembled. A treatment cycle of four hours at 250^{O}F was required to kill the indicator organisms on the reassembled equipment. One hour of treatment was sufficient to kill the indicator spores on the disassembled equipment parts.

Cole et al. (1993)

Cole et al. (1993) evaluated laboratory as well as larger autoclaves to determine their efficacy. The results of laboratory and field tests showed steam autoclaving to be effective in treating biomedical waste. Laboratory data showed that high level challenges (with blood serum) of various organisms in surrogate waste loads were readily inactivated by relatively low temperature (104^{o}C), short term (5 min) exposure to the steam autoclaving process regardless of direct steam contact. Additionally, both laboratory and field data showed that high concentrations of bacterial spores were readily inactivated at a setting of 121^{o}C by exposure to the combined effects of steam, heat, and pressure.

III. Qualitative comparison of the treatment of clinical waste by incineration and by steam autoclaving

A discussion on incineration is provided below in addition to the attached chart of comparative information on a number of treatment technologies.

Discussion on Incineration

By the U.S. Environmental Protection Agency's (EPA) estimate, the nation's 7,000 hospitals own 2,400 hospital/medical/infectious waste incinerators (HMIWI).[1] Many of these facilities may no longer be operating.[2] An HMIWI is defined by the EPA as "any device that combusts any amount of hospital waste and/or medical/ infectious waste."[3] HMIWI range in hourly capacity or "charge rate" from 20 to as high as 3,000 lbs./hour. Generally, the range is 50 to 500 lbs./hour.

Incinerators use high temperature (1,100 to 2,000^{o}F) combustion to destroy biomedical waste. Most HMIWI are two-stage, controlled air units. Rotary kiln technology has been put into use in newer units. Modern incinerators are better engineered than units constructed more than ten years ago. This results in better efficiency and lower emissions. However, it is likely that a majority of the HMIWI currently in operation is more than ten years old.

In two-stage HMIWL the first stage chamber is where solid wastes are combusted. This chamber typically operates within a temperature range of 1,100 to 1,400^{o}F. In the second stage, the combustion gases from the first stage combusted again. The gases remain in the second stage chamber for one-half to two seconds at a temperature of 1,600 to 2,000^{o}F. This is generally sufficient to destroy any unburned volatile compounds and ensure complete destruction of any microorganisms.

Historically, incineration has been the method of choice not only for disposal of biomedical waste but general hospital waste as well. This began to change with the advent of disposable plastics four decades ago. Higher incinerator emissions resulted since most HMIWI were not designed or tuned to deal with the subsequent high Btu waste. The strict air emissions standards of the 1990 amendments to the Clean

Air Act (CAA) forced many incinerator operators to shut down their units rather than pay for expensive emissions control equipment. In September 1997, the EPA promulgated sections 111 and 129 of the CAA to further address the issue of air emissions from HMIWI. The EPA estimates that as many as 80 percent of HMIWI will be forced to shut down by September 2000 due to the new standards. [4]

Capital and O&M costs for HMIWI can be quite high. However, payback is short due to the ability of HMIWI to dispose of all types of waste, not just MIW. In many cases, these results in processing costs (including amortization of capital) lower than for off-site hauling or some alternative technologies.

According to the EPA, large HMIWI (over 500 lbs/hour) can cost $120,000 per year to operate, while small HMIWI (less than 200 lbs./hour) can cost $35,000 per year to operate. The EPA estimates that current incineration costs average $0.16/lb for hospitals. This cost does not include labor but does include utilities and amortization of capital.

The costs of compliance with the new HMIWI standards are quite high. The EPA acknowledges that for most HMIWI operators, except those operating in "rural" areas it would be more economical to switch to an alternative treatment technology rather then retrofit their existing HMIWI to meet the standards.

According the to the EPA, emissions testing can cost as high as $30,000 and dry scrubbers can cost as much as $250,000.[7] The addition of air pollution control devices can add $150,000 to $300,000 per year to the operating costs of a large HMIWI, while they can add $10,000 per year for small HMIWI.

By the EPA's own estimates, compliance with the new HMIWI standards could increase incineration costs by at least 21 percent and as much as 75 percent, depending on the scenario modeled. These increased costs of operation will result in increased patient care charges. However, the EPA estimates that the cost increase to the patient will amount to less than 300 per day.

References:

1. Memorandum from Brian Strong, Midwest Research Institute, to Richard Copeland, USEPA ESD Combustion Group, May *20, 1996,* "Updated Medical Waste Incinerator Database."

2. State of New York - 300+ incinerators operational in 1989, less than 10 operational in 1999. State of Connecticut – 30+ operational in 1989, 2 operational in 1999

3. "Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital Medical/Infectious Waste Incinerators; Final Rule - 40 CFR Part *60," Federal Register, Vol. 62,* No. *178,* September *15, 1997, U.S.* Environmental Protection Agency.

4. "Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Medical Waste Incinerators; Proposed Rule - 40 CFR Part *60," Federal Register, Vol. 61,* No. *120,* June *20, 1996, U.S.* Environmental Protection Agency.

IV. Environmental impacts of steam autoclaving including the aesthetic issues

Air Emissions

Until recently, the emissions of gaseous and particulate contaminants from medical waste treatment technologies have not been well characterized. VOCs are expected to be components of medical waste, and may be formed and emitted during the treatment process. An earlier study (Jones, et al. (1994) attempted to qualify and quantify the emissions from alternative technologies. That study concluded direct inhalation cancer risks are comparable for the incineration and autoclave alternatives if the dispersion characteristics are similar [1]

A 1997 National Institute of Occupational Safety and Health(NIOSH) report[2] evaluated a number of alternative treatment technologies for the potential release of aerosols and chemicals in medical waste treatment facilities. The conclusions from that study indicated the following:

- Several VOCs were observed in each facility, but no Occupational Safety and Health Administration(OSHA) Permissible Exposure Limits(PEL) or American Conference of Governmental Industrial Hygienist(ACGIH) Threshold Limit Values(TLV) was exceeded.

- Formaldehyde concentrations were below the OSHA PEL and lower than the ACGIH TLV mg/m3 (ceiling limit), but above the NIOSH Recommended Exposure Limit.

- In the autoclave and microwave facilities, acetaldehyde and acetone were also observed, but at concentrations several orders of magnitude lower than their respective PELs

- Short-term, high concentrations of ammonia, not emanating from the medical waste, were found in the autoclave facility.

- The metals sampling for all three facilities indicated minimal levels (most less than the detection limits), of the following metals, Be, Al, Cr, Mn, Fe, Co, Ni, Zn, Cu, As, Se, Ag, Cd, Sb, Ba, Tl, Pb and Hg. The pyrolysis facility also showed minimum levels of P.

- No chlorine was detected in the air in the autoclave or mechanical/chemical facilities. (The other sites were not tested as no sources of chlorine were known.)

- The indoor air quality evaluations for temperature, humidity, carbon dioxide (CO2), and carbon monoxide (CO) indicated adequate indoor air during sampling, although one facility needs to monitor the CO levels on less drafty days.

Treated Autoclave Waste Disposal

The solid waste discharged from autoclaves is often considered sterile. Some systems only compact the wastes, although a shredder option is available. Other systems shred or grind waste as part of the treatment process. Most regulatory agencies do not prohibit the disposal of treated only waste. However, certain items of the waste stream may require additional processing. Specifically, sharps, which may retain a physical hazard, should be destroyed. This removes the potential for injury and the potential for scavenging should treated waste be placed in an unsecured waste disposal area.

As was stated previously, most types of clinical waste are treatable by an autoclave. Also, wastes remain recognizable unless a shredder is used, further limiting the types of wastes that are treatable. In particular, volatile and semi-volatile organic wastes, chemotherapeutic wastes, and other toxic chemical wastes cannot be treated by an autoclave system. These wastes, along with radiological wastes, must be processed by other means. Treatment of pathological waste by autoclaves is not recommended due to the lack of penetration of steam into dense tissue and bones. However, there are some hybrid autoclave systems (Hydroclave and Tempico) that are now suitable for processing of pathological waste. Data is available that supports the processing of pathological waste through these two systems. Disposal of anatomical waste has been customarily done by incineration or interment.

Limitations on the type of medical waste standard autoclave (with the exception of the Tempico and Hydroclave designs) will accept may require the user to alter its waste handling procedures, separating certain types of wastes at the source. Additional costs may be incurred for transportation and treatment of these excluded wastes.

References:

1. A Comparative Life Cycle Risk Assessment of Regulated Clinical waste Incineration and Thermal Treatment, Jones, K., Konheim, C.S., 87th Annual Meeting of the Air and Waste Management Association, June 19-24, 1994

2. Control of Aerosol (Biological and Non-Biological) and Chemical Exposures and Safety Hazards in Clinical Waste Treatment Facilities

V. Issue of residue disposal (e.g.. suitability of autoclave waste for landfills)

Infectious Agents in Solid Waste

This section examines the issue of residue disposal of autoclaved waste into the solid waste stream. This will focus on the waste stream from the point of waste collection to final landfill disposal. This section examines the presence of infectious agents in the waste stream, potential disease transmission through direct contact, aerosols, surface/ground water, and biological vectors.

Presence of Infectious Agents

Tortora et al. defines the criteria for a reservoir of infection as "a living organism or an inanimate object that provides a pathogen with adequate conditions for survival and multiplication and an opportunity for transmission"[9]. In the broadest sense, the solid waste stream should be viewed as a reservoir of infection, though exceptions to this can be found. The discussion to follow will be based upon the potential for the solid waste stream to act as an intermediary fomite (non-living object) in transmitting infectious agents from reservoirs of infectious agents to human hosts.

The presence of human infectious microbial agents in the solid waste stream has been well established in the literature [50-57]. Peterson reports that three 30 gram samples of solid waste (in duplicate) are required to yield a pathogen positive sample[57].

Lynch and Jackson report that, "Body substances such as feces, airway secretions and wound drainage always contain potentially infectious organisms, and blood, urine and other moist body substances sometimes do as well"[16]. Day to day wastes, whether from medical institutions or homes, may contain human pathogens entered into the waste stream from human excreta from disposable diapers, animal excrement, blood, exudates or secretions from dressings, bandages, or sanitary napkins, facial tissue, condoms, bandages, home used syringes or other inanimate objects that have come into contact with

human body substances. Gaby reports that the microbiological flora of solid waste has been judged to be equal to that of sewage and the upper respiratory tract of man [55].

Few studies have been conducted to compare the microbial loads of waste from residential sources in comparison to hospital sources. Of the studies that have been conducted, taking into account sampling and assay limitations, the microbial loads of the general household waste equal and exceed microbial loads observed in hospital wastes [58-60].

It is evident from a review of the literature that any waste source, whether from medical or residential origin, can contain microorganisms that, under the right circumstances, could cause infection in a susceptible host.

Contact with Infectious Agents

In 1987, Turnberg examined the waste stream to determine common routes of exposure to humans[61]. The waste stream was observed from waste collection areas through solid waste transfer stations to final landfill disposal to identify exposure patterns. Public exposure to the waste stream was concluded to be low if solid waste storage and disposal regulations are observed. Occupational exposure to waste worker groups, particularly by direct contact, was observed as a routine part of employment.

In 1982, the National Institute for Occupational Safety and Health reported on the potential for infectious disease transmission to residential waste collectors from direct contact with the waste stream[62]. The report stressed personal hygiene as a health matter of considerable importance to this group and recommended that employees bathe daily, wash before eating during the day and before going home. The report recommended that employers address proper techniques for cleaning and covering wounds and that clean gloves and coveralls be provided daily by employers.

In a 1987 publication, the Health Division of the Oregon Department of Human Resources further recommended that protective safety equipment be employed by waste workers to add further

protection against potential infectious disease transmission[63]. Protective measures include use of safety glasses, hard hats with chin straps, coveralls, waterproof gauntlet gloves, boots with sufficient thickness and strength to protect the wearer from injury from sharp objects and NIOSH approved dust masks when working indoors (e.g. at a transfer station) or whenever necessary. The report also urged waste worker employees to report all injuries and illness to the person responsible for employee health.

Proper employment of hygiene practices and safety equipment by waste industry workers will significantly reduce direct contact exposure to infectious agents in the waste stream. Orientation and on-going educational programs by employers are advised.

Ground/Surface Water Contamination

The presence of pathogenic microorganisms and microbes of sanitary significance in solid waste has been established in the literature. Concern has been raised regarding potential human health implications regarding the release of these agents from sanitary landfills to the environment. This section will examine the literature regarding the survival and release of these agents to surface and groundwater.

The health significance of pathogenic microorganisms in landfills has been described as related to:

- The concentration and nature of the pathogen;
- The pathogen's ability to survive and retain its infectious properties in the landfill environment; and
- The pathogen's ability to migrate through the landfill into the surrounding environment and be a potential human hazard[64].

Concentration and Nature

The presence of infectious agents and microorganisms of sanitary significance in the waste stream has been established. However studies that specifically characterize the concentration and nature of pathogens in the waste stream and landfills are limited. Several studies have been published that have quantified indicator organisms of fecal pollution (total coliform, fecal coliform and fecal streptococcus) from leachate derived from field or simulated sources [54,55,64-70].

The substantial presence of fecal waste in landfills from human and animal sources has been suggested based upon indicator bacterial recoveries[54,67]. This indicates the presence of pathogenic microorganisms associated with fecal waste.

Enteric pathogenic bacteria have been identified from leachate sources, but not enumerated [55,70]. Enteric virus particles, including polio virus, have also been isolated from landfill leachates, though one study that examined leachate samples collected from 22 landfill sites isolated enteric virus particles (polio type 1 and 3) from only one site which was described by the author as having deficient sanitary landfill practices [70]. Further study to characterize pathogenic microorganism populations in solid waste, landfills and landfill leachates are needed.

Pathogen Survival in the Landfill Environment

Several studies have been published in the literature that examine the survival of microorganisms in landfills and landfill leachates. In 1972, Peterson published "pioneering" research examining poliovirus survival in the landfill environment [52]. The author seeded an area of new landfill material at various depths and observed that the virus was inactivated at all depths within 2-4 days. This was attributed to the sharp temperature increases of up to 140o Fahrenheit that is typically associated with the initial

aerobic decomposition of waste in a landfill. This phenomenon has been observed by other researchers [55,65,72,73]. Peterson identified other potential antagonisms to the survival of microorganisms in a landfill as chemical contaminants such as pesticides, drugs or heavy metals, though none could be correlated to the inactivating process [52].

Englebrecht et al. observed a significant decrease of bacteria and an absence of virus from leachate derived from a laboratory lysimeter simulating a landfill environment. These results indicated that the harsh conditions of landfill leachate have an inactivating effect upon certain microorganisms[63]. However, the author could not correlate the inactivating constituents.

In a field examination of leachates from 22 landfills, Sobsey could isolate virus from only one site that was described as poorly operated [71]. Based on these findings, the author suggested that leachates from properly run sanitary landfills pose little threat to the public with regard to infection by enteric virus.

In 1981, Donnely et al. published a report on the recovery of fecal indicator and pathogenic microbes from landfill leachates and laboratory lysimeters simulating landfill conditions [57]. The author demonstrated that leachate contained Gram-negative rods, all potentially present in human feces and several potentially pathogenic agents. Fecal indicator bacteria were isolated from older landfill sites indicating their potential survival for long periods of time.

Pathogen Migration to Groundwater

Viruses and bacteria that survive the chemical and physical characteristics of the landfill environment still face other hurdles. Movement of these microorganisms through soils of the landfill would be dependent upon many factors, including soil texture/composition, soil moisture, salt concentrations, pH, climate (rainfall and temperature), nutrient availability and antagonisms [56]. Absorption of viruses onto fill material is likely and may also explain the low recovery of viruses from landfill leachate studies.

Sobsey conducted an examination of viral particles in leachate obtained from a seeded laboratory lysimeter simulating laboratory conditions. No viral particles could be recovered though more than 80 percent of the test leachate had been tested. The author suggested that the viruses were either inactivated or adsorbed onto refuse components [71]. Based on a review of literature sources, Ware reports that the adsorption of virus particles onto fill material is likely and may partly explain low recovery rates from leachate [56].

Novello observed that 10 centimeters of gravelly, silty sand could remove from 80 - 98 percent of poliovirus in leachate. The author suggested that if a virus could survive and find its way into a leachate, that the soil underlying a landfill could filter these particles out [73]. Rogers support this premise [74].

U.S. Federal Solid Waste Regulations

Landfilling of our society's solid waste remains the most widely used and accepted method for waste disposal. In 1991, the U.S. Environmental Protection Agency promulgated minimum landfill standards that must be adopted and implemented by each state [75]. These requirements specify how landfills are located and operated. The standards address how municipal solid waste landfills are sited, constructed, operated, closed and cared for during a 30 year post-closure period to ensure that the environment is protected.

The standards were largely written to protect ground and surface water from leachate pollutants. In doing so, EPA established requirements for landfill liners, leachate collection systems, compaction and covering of waste and environmental monitoring. The operation of sanitary landfills has become far more sophisticated in terms of protecting the health of the public and environment in comparison to the open dumpsites of only twenty years ago.

In conclusion, the risk associated with ground and surface water contamination by infectious microorganisms in a properly operated landfill appears to be low. This premise is supported in the literature though further examination of this issue is needed.

Biological Vectors

Concern has been expressed regarding the potential role of biological vectors in the spread of infectious disease from landfill sites [52]. Potential vectors include rodents, insects, birds and wild or domestic animals. The importance of biological vectors in terms of disease transmission and human morbidity is well established [49]. Reports in the literature of biological vectors disease transmission from solid waste stream sources are virtually non-existent, based on this review.

The control of vectors at landfill sites has been addressed by current federal solid waste standards [75]. On-site containerized storage, collection and transportation standards for solid waste disposal have addressed the prevention of vector harborage, proliferation and access. Landfill sites must be fenced to prevent the unauthorized entrance of the public or animals. Controls must also be in place to prevent the harborage and presence of vectors such as rats, insects, birds and burrowing animals.

Risks associated with vector borne disease transmission have been addressed by current federal solid waste standards. The absence of current morbidity statistics or documentation in the literature regarding vector disease transmission associated with waste disposal indicates the risk to be low. However, it is an area that requires further study.

Infectious Aerosols

It is well established that aerosols containing pathogenic microorganisms can cause infectious disease, particularly in laboratory settings [76-79]. The ability of an aerosol to cause infection by inhalation is related to the susceptibility of the host and the infective dose and virulence of the pathogen. With regard

to indoor microbial aerosols, Spendlove and Fannin report that despite the considerable volume of data available, that little is known about true significance to health except in terms of overt epidemic disease [80].

The role of infectious aerosols originating from the solid waste stream in terms of human morbidity is less understood and supporting studies are limited. Two studies have been identified that focus on the subject. Ducel et al. conducted an examination of aerosols associated with waste collection and their effects on the workers [81]. The authors concluded that reports of the start and continuation of chronic bronchitis could be associated with exposure to airborne infectious agents.

Fiscus et al. examined airborne levels of bacteria and viruses at a refuse processing plant, a municipal incinerator, a waste transfer station, a landfill and a wastewater treatment plant [82]. No viruses were isolated during the study, which may actually reflect more on the limitations of the assay recovery system than on the absence of airborne virus particles. The highest levels of airborne bacteria colonies were observed at the refuse derived fuel facility, both within the facility and at the property line. The health significance of any of the observed levels could not be determined.

The study also involved a comprehensive literature review to determine existing information regarding bacteria and virus emissions from waste handling facilities. The authors identified studies observing airborne bacterial colonies ranging from 200/cubic meter in a laboratory, up to 700,000/ cubic meter in a sewage treatment plant and between 2,000 - 4,000/cubic meter in offices, factories and streets. Again the authors stated that the health significance for any of these levels could not be judged, based on the existing literature.

Disease Transmission

The Centers for Disease Control reports "There is no epidemiological evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiological

evidence that hospital waste disposal practices have caused disease in the community" [83]. Rutala further states that (with the exception of sharps) there is only one instance of infectious waste associated with in-hospital transmission of infection [59]. This one case involved disease transmission from a chute-hydro pulping waste system in a hospital [84].

Medical waste disposal has emerged as a concern for waste industry workers. The AIDS epidemic has elevated the awareness and fear of this group regarding potential disease transmission through waste stream sources, particularly hospital waste, though such disease transmission has never been epidemiologically demonstrated [13].

Few studies have been conducted to examine waste industry worker exposure to potentially infectious agents in the waste stream. Gellin and Zavon examined 97 waste workers employed by the City of Cincinnati during January and February of 1968 for skin disorders [85]. Forty-one cases of bacterial, viral or fungal dermatitis were observed in this group, but all were classified as non-occupational in origin. The authors reported that no systemic infectious diseases had been diagnosed in the Cincinnati Division of Waste Collection at the time of their study and that only one claim had been filed for occupational skin disease that was later judged to be non-occupational in origin.

Cimino examined New York City Sanitation Department health records of waste workers employed between 1968-1969 [86]. Needlestick injuries were reported due to the presence of uncontained needles in waste collected from hospitals, doctors and dentist's offices, and discarded needles from drug addicts. All workers reporting needlestick injuries were given gamma globulin prophylaxis and no cases of hepatitis were reported.

Cimino's subsequent 1987 publication of occupational hazards from New York City sanitation workers examined death records between 1975-84 for those employed as solid waste collectors as of January 1973 [87] . Of those 10,565 individuals, 511 died during that period. The author did not report any deaths or illness due to infectious disease.

A 1979 report by Clark et al. examined the incidence of viral infection among 44 waste collection workers [88]. Sera antibody levels for eighteen viruses were examined from blood samples collected during the spring and fall. The authors found no evidence for an increased occupational risk to bloodborne viral infections.

In a 1990 report by Turnberg and Frost, 940 waste industry workers were surveyed to evaluate occupational exposure to potentially infectious materials in the municipal waste stream [89]. Responses were received from 438 (47%) of the 940 workers surveyed. Waste worker employee job safety training rates were ascertained as well as occurrences of occupationally incurred cuts and scratches. The prevalence of exposure to blood contaminated waste and injury from hypodermic needles were also estimated. Sixty-nine per cent of respondents reported having received job safety training but only 26% were trained specifically to deal with safety hazards associated with medical waste. Seventy-four per cent of respondents reported having received cuts and scratches on-the-job and 32% of respondents reported direct contact with waste blood on their clothing or shoes. Thirteen per cent of respondents reported blood exposure on their skin and 5% reported blood exposure on their face or eyes. Occupational needlestick injuries were reported by 21% of respondents overall, with 10% of 240 responding waste collectors reporting having sustained a needlestick injury in the year preceding the survey. Needlesticks were reported from both residential and commercial waste collectors as well as by landfill/transfer station operators. Though injuries were reported, none was linked to infectious disease transmission.

Summary

In summary, the published literature provides no information linking the solid waste stream with infectious disease transmission, though it must be acknowledged that studies on this subject are limited. Therefore, it is also safe to assume clinical waste treated by autoclaving to reduce or eliminate the concentration of microorganisms in the waste stream is no more likely to be a risk to public and

environmental health than solid waste. Data is provided on the potential risks associated with working in a clinical waste treatment facility in the appendices.

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VI. Use of autoclaving in the USA and other countries

As was stated earlier, autoclaving is a proven technology that is accepted by all 50 states as a method of treating clinical waste. Their wide acceptance and extensive market share make autoclaves the technology to which all other clinical waste treatment systems are compared.

The estimated number of autoclaves in the United States and abroad (# = 1,079) is based upon data from an Infectious Waste News survey conducted in 1998. Numbers have increased since the publication of the data.

Company	Years In Business	Operating Units North America/Abroad
The Antaeus Group	**6**	**4/0**
Bondtech Corp.	**14**	**75/5**
Environmental Tectonics	**6**	**10**
Hydroclave (Canada)*	**7**	**7/6**
Lajtos (France)	**5**	**0/19**
Mark-Costello Co.	**25**	**225/75**
San-I-Pak, Inc.	**19**	**400/25**
Tempico, Inc.	**7**	**20/7**
Tuttnauer USA Co. Ltd.	**2**	**42/170**

Source: *Infectious Waste News, Vol.* 13, No. 12, June 8, 1998, pp. 4-5

*** Data as of November 2001**

VII. Applicable operating standards

Effective treatment requires knowledge of many factors relating to the treatment process. These include the type of unit, type and volume of wastes to be processed, waste packaging, and placement in the chamber. Skilled, trained steam sterilizer operators are essential. Training should be provided by the employer and include proper autoclave operation as well as potential associated hazards (e.g., chemically toxic or radioactive wastes should never be autoclaved). Processing effectiveness should be monitored to ensure that treatment has been accomplished using time/ temperature charts, chemical indicators that produce color changes to correspond with the necessary time-temperature relationship to achieve sterilization, and biological indicators (e.g., spore strips of *Bacillus subtilis* or B. *stearothermophilus)* to ensure inactivation of the most resistant microorganisms. Only such monitoring will provide the operator with the knowledge regarding operational parameters that is necessary for an autoclave to treat a given waste load effectively. All units should be inspected and serviced routinely to ensure optimum operation. An adequate system of record keeping should also be in place not only for internal purposes, but also for evidence of proper processing if requested by government regulators or accreditation organizations.

Effective standardization of the steam sterilization process is essential to assure treatment effectiveness. Five factors must be considered:

1. Conscientious, dependable, skilled operators
2. Correct methods of packaging to ensure steam penetration of the load
3. Proper loading of the unit
4. Approved sterilizer with demonstrated reliability
5. Adequate exposure period-that provides complete steam penetration of the entire load and ensures microbial destruction with a safety margin

The factors identified in the literature (Rutala et al., 1982; Lauer et al., 1982; Glick et al., 1961) which affect the efficiency of the autoclave treatment of medical waste are those affecting temperature inside the waste load, steam penetration into the waste and the duration of treatment. These factors include:

- temperature and pressure achieved by the autoclave
- the size of the waste load
- the composition of the waste load
- the steam penetration of the waste
- the packaging of the waste for treatment
- the orientation of the waste load within the autoclave

At a given temperature, the length of time of treatment is the variable that determines the extent of heat and steam penetration to the center of a load. Minimum recommendations for the treatment of clinical waste by autoclaving Include 121^{o}C, 15 psi for 45 minutes (Rutala et al., 1982) and for 50 minutes (Lauer et al., 1982).

The New York Department of Health requires autoclave treatment facilities (hospital or commercial) to follow the treatment parameters described below:

For gravity type autoclaves:

250^{o}F (121^{o}C) @15 psi for no less than 60 minutes
275^{o}F(135^{o}C) @31 psi for no less than 45 minutes

300°F(147°C) @ 52 psi for no less than 30 minutes

For vacuum type autoclaves:

250°F (121°C) @15 psi for no less than 45 minutes

275°F(135°C) @31 psi for no less than 30 minutes

Note: Autoclaves as well as other treatment technologies utilizing different treatment parameters (e.g., cycle time, temperature, and pressure) that achieve the levels of microbial inactivation as described in the State and Territorial Association on Alternative Treatment Technologies (STAATT II) report may also be used for the treatment of medical waste.

VIII. Waste exclusions and/or limitations (e.g.. viability of using autoclave for human tissues);

Traditional autoclave systems treat infectious wastes with steam. However, they do not greatly alter the physical make-up of the waste. Wastes remain recognizable unless a shredder or maceration process is used. Depending on the jurisdiction, there may be a requirement to make waste unrecognizable or reduced in volume due to economic reasons (space limitations at landfills). Not all types of waste are treatable by this method as well. Pathological waste that is not macerated as part of the treatment process (via a Hydroclave or Tempico system), hazardous chemotherapeutic wastes, and other toxic chemical wastes cannot be treated by an autoclave system. These wastes, along with radiological wastes, must be processed by other means.

The limitations on the type of medical waste these systems will accept may require the user to alter its waste handling procedures, separating certain types of wastes at the source. This generator of such waste may be required to find alternative methods of disposal including off-site shipment of waste. This may also involve the modification of certain waste handling procedures.

The composition of the waste stream entering these systems (i.e., percent of plastics, liquids, noncombustibles, etc.) does not affect their ability to properly treat the waste. However, some autoclave systems have limits on the amount of liquids they can process. Identified below are the categories of clinical waste (per the EPA Medical Waste Tracking Act of 1988) whether they can be treated by an autoclave.

Class 1 - Cultures and stocks

Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated

vaccines, and culture dishes and devices used to transfer, inoculate, and mix cultures (hereinafter referred to as microbiological waste).

All waste items in this category are suitable for treatment by autoclave except tightly capped bulk liquids that are not permeable by steam and heat up slowly.

Class 2 - Pathological wastes

Human pathological wastes, including tissues, organs, and body parts, and body fluids that are removed during surgery and autopsy or other medical procedures, and specimens of body fluids and their containers.

Human organs and body parts removed during surgery or autopsy are not suitable for treatment by standard autoclaves. Hybrid systems have been proven to be effective. Otherwise, all other wastes in this category may be treated by this technology.

Note: Waste liquid formalin should be managed as a hazardous waste and not placed in any medical waste treatment system.

Class 3 - Human blood and blood products

Waste human blood products of blood, Items saturated and/or dripping with human blood; or Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use In either patient care, testing and laboratory analysis, or the development of pharmaceuticals. Intravenous bags are also included in this category.

Tightly closed containers of bulk liquids that are impermeable to steam and slow to heat up are not suitable for treatment by standard autoclaves. Operation of hybrid autoclaves addresses this issue by

maceration of the container or containers. All other waste items in this category are suitable for treatment by autoclave.

Class 4 - Used sharps

Sharps that have been used in animal or human patient care or in medical, research, or industrial laboratories, including hypodermic needles, syringes, Pasteur pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

All items in this category are suitable for treatment by autoclave. Care must be exercised in placing sealed sharps containers into gravity type autoclaves. Placement of containers (vertical versus horizontal can impact the efficiency of treatment when utilizing a gravity autoclave.

Class 5 - Animal wastes

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

Contaminated animal carcasses and body parts are not suitable for treatment by autoclave with the exception of hybrid autoclaves. Other waste items in this category may be treated by this technology.

Note: Waste liquid formalin should be managed as a hazardous waste and not placed in any medical waste treatment system.

Class 6 - Isolation wastes

Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from highly communicable diseases or isolated animals known to be infected with highly communicable diseases.

All wastes in this category are suitable for treatment by autoclave.

Class 7 - Unused sharps

Unused sharps include the following unused, discarded sharps as a class of regulated clinical waste; hypodermic noodles, suture needles, syringes, and scalpel blades.

All Items in this category are suitable for treatment by autoclave.

IX. System capacities/Economical data/information

The following section contains general information on several of the more common autoclaves available on the market today. This information includes:

- Capacity
- Treatment Costs
- Capital Costs

Note: Information provided by vendors. . The list is not all-inclusive.

Company	Capacity (pph)	Treatment costs (cents/lb.)	Capital Cost (in thousands of dollars)
The Antaeus Group	**150**	**4**	**$200**
Bondtech Corp.	**250-3000**	**5-7**	**$100-$175**
Environmental Tectonics	**400-2000**	**3-8**	**$150-$275**
Hydroclave (Canada)	**220-2200**	**2**	**$63-$400**
Lajtos (France)	**17-30**	**1**	**$156-$306**
Mark-Costello Co.	**225-1125**	**6**	**$26-$45**
San-I-Pak, Inc.	**25-3000**	**4**	**$35-$600**
Tempico, Inc.	**208-1370**	**5**	**$150-$1.7million**
Tuttnauer USA Co. Ltd.	**70-2000**	**2**	**$50-$300**

Source: *Infectious Waste News, Vol.* 13, No. 12, June 8, 1998, pp. 4-5 + personal communication

We are aware that Dominica has expressed interest in an incinerator. We would be interested in acquiring costs associated with that system being considered. We have obtained costs on two systems and present data below. Utilities can include electricity, gas, and water. Utility requirements for two systems are presented below.

Tempico 2500-D2 Rotoclave System Utility Requirements - 1,000 pounds of waste per hour

Electricity: 200 A, 480 V, 30
70 A, 230 V, 1~~o~~
Two 5 A, 120 V
Two 15 A, 120 V

Sewer: * 70 gallons per cycle (steam condensate and liquid waste)

Cooling Tower Water:	* 1,000 gallons @ 120 gpm, 85'F (per cycle)
Steam:	600 lbs/hr or less @ 60 psig (per cycle)
Instrument Air:	5 scfm @ 100 psig (per cycle)
City Water:	90 gallons per cycle

Tempico 2500-D2 Rotoclave Installation, Operating, and Maintenance Costs

Item	Annual	Costs per Unit of Waste (cents/lb.)
Operator Labor	$42,750	1.5
Maintenance	$79,100	2.7
Utilities (electric, gas, water)	$24,220	0.8
Consumables	$0	0.0
Disposal Costs	$127,989	4.3
Totals without Amortization	$274,059	9.3 0/lb
Amortization of Capital	$147,353	5.0
Totals with Amortization	$421,412	14.3/lb

Note : This assumes processing of 2,947,368 pounds of clinical waste per year

San-I-Pak Model 241L System Required Utilities (160 pounds per hour)

Electricity	60 A, 240 V, 3o
Steam	5 lbs/hr @ 65 psig
City Water	30 gallons/hour

San-I-Pak Model 241L Installation, Operating, and Maintenance Costs

Item	Annual	Costs per Unit of Waste (cents/lb.)
Operator Labor	$13,552	2.9
Maintenance	$11,600	2.5
Utilities (electric, gas, water)	$1,722	0.4
Consumables	$7,000	1.5
Disposal Costs	$19,806	4.2
Totals without Amortization	$53,680	11.40/lb
Amortization of Capital	$21,609	4.6
Totals with **Amortization**	$75,290	16.00/lb

This assumes processing 471,579 pounds per year (600 kg/day)

Reference for Data: Vendor information from Tempico and San-I-Pak

Additional Cost Comparison Chart

	Sterilization	**Incineration**	**Specialized Handling**
	Mark –Costello Waste Sterilizer	750 Lb. Gas Incinerator With Air Pollution Control Equipment	Off-site Hauling
Approximate Equipment Purchase Price	$34,000[1]	$250,000	----
Annual Expenses			
Maintenance	$700.00	$5,225.00	----
Fuel & Electricity	$400.00[3]	$6,050.00[2]	----
Direct Labor@ $10/Hour	$5,475.00	$5,475.00	$3,650.00
Depreciation/ 15 years	$2,270.00	$16,660.00	----
Autoclavable Bags	$2,650.00	----	----
Container Rental	----	----	$2,000.00[4]
Hauling-Disposal Cost	$8,200.00	(ash) $5,000.00	$98,550.00[5]
Total Estimated Annual System Cost	**$19,695.00**	**$38,410.00**	**$104,200.00**

Note: [1] Based on a price of a medium sized Mark-Costello Waste Sterilizer with carts, Model AS47
[2] Based on one cycle per day, 365 days, 750 lbs./day
[3] Based on two cycles per day, 365 days, 900 lbs./day
[4] Fees may not always be charged for containers/trailers
[5] Based on 900 lbs. waste daily, 365 days, @ $.30 per pound

Data/information on the autoclave does not take into account that a portion of the waste stream may not be treated by the system. Pathological and hazardous chemotherapuetic waste

(5-10% of the medical waste stream) will need to be treated by incineration or other acceptable method.

The Mark Costello Waste Sterilizer

General Operating Data

Steam Usage

The sterilizer steam demand is:

Small & Medium Standard Sized Units -	100 lbs. per cycle
Large Standard Sized Units -	150 to 200 lbs. per cycle

Steam Availability

Hospital steam source is normally adequate. If hospital sources are unavailable within reasonable proximity to the location of the sterilizer, a self-contained steam generator may be utilized. The same applies to other applications where high-pressure steam is not available. The correct HP boiler should be engineered according to the application

Electrical Requirement – 115V, Single Phase, 5 Amperes

Steam Requirement - 60 PSIG regulated steam supply

Operational Cycle Time

One hour at sterilizing temperature is recommended. Other cycle times may be utilized in accordance with Federal State or Local regulations.

Total Cycle Time - Approximately 11/2 hours

Normal Recommended Temperature Setting – 275^{o}F

Unit Durability

Unit is constructed of heavy-duty components and materials. Useful life of vessel estimated at 15 to 20 years if properly operated and maintained.

Maintenance

Should be less than $1,000.00 per year if properly operated and maintained.

Analysis of Cost Comparison Chart

Using the numbers on the previous pages, one can derive the cost per pound for each of the three systems. For the Mark-Costello sterilizer and the specialized hauling we are assuming 900 lbs. per day for a *365* day year. For the incinerator we are assuming 750 lbs. day for a 365 day year. Hauling costs for general waste varies widely, depending upon many factors such as region, compaction density, moisture content, etc. For purposes of this data we are assuming 2 1/2¢ per lbs. Hauling costs for Regulated Medical Waste also vary widely but information from haulers and hospitals have shown an average range 25¢ -30¢ per lb. ($0.15/lb. minimum/$0.45 maximum)

Plugging in the numbers, we arrive at the following costs per lb.:

Mark-Costello Waste Sterilizer
900 lbs. x 365 days = 328,500 lbs./year
$19,695/328,500 lbs. = $.06/lb

750 lb. Gas Incinerator
750 lbs. x 365 days = 273,750 lbs./year
$38,410/273.750 = $.14/lb.

Specialized Hauling
900lbs. x 365 = 328,500 lbs./year
$104,200/$328,500 lbs. = $.32/lb.

Reference:

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February 16, 2000

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