FINAL
TECHNICAL REPORT

HEALTH AND SAFETY ASSESSMENT OF THE *Rotoclave*® MEDICAL WASTE TREATMENT TECHNOLOGY

Prepared for

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The goal of the Cooperative Research and development agreement (CRADA) was to access the Rotoclave® medical waste treatment system by evaluating the worker environment with regards to safety, aerosol, chemical, blood and microorganism hazards and the use of the engineering controls in controlling exposures. A previous National Institute of Occupational Safety and Health (NIOSH) study, "Control of Aerosol (Biological and Nonbiological) and Chemical Exposures and Safety Hazards in Medical Waste Treatment Facilities" conducted the same assessment for four different alternative treatment technologies. The evaluation of the Rotoclave® system, an additional alternative, was conducted to expand the original base of information generated by that study. DynCorp wishes to thank Dr. Paul Jensen of NIOSH for his technical guidance and assistance.

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EXECUTIVE SUMMARY

Objective. This study was conducted by DynCorp Health Research Services, a contractor, as part of a NIOSH CRADA with Tempico, Incorporation, of Madisonville, LA. The purpose of this study was to evaluate chemical, biological, and particulate emissions from the Rotoclave® medical waste treatment technology during waste processing, and to identify and quantify health and safety hazards and potential exposures to the workers interfacing with the system.

Background. The Rotoclave® technology combines steam autoclaving of the waste while appropriately rotating it so that the contents of the waste containers are uniformly exposed to the steam. Following the treatment cycle, the waste is moved from the unit via conveyor to a solid waste shredder and then through a grinder for final disposition to a landfill. The technology is designed to treat most types of Regulated Medical Waste (RMW), to include animal bedding, animal carcasses, sharps, and glass tubes. It is not designed to treat hazardous chemical wastes or radioactive wastes.

Approach. The study was conducted on-site at a large medical center in the southeastern United States, where two Rotoclave® units enclosed in one room of a building were run continuously throughout the day shift to process potentially infectious wastes. One full time person loads the units during the day and oversees their overall operation. All monitoring, evaluations, and assessments were conducted over a two day period, December 3-4, 1997. Additionally, observation and documentation of an automatic waste loader was conducted at a second facility on February 17, 1998. The work was carried out by a team of four technical professionals to include: 1) a certified industrial hygienist (CIH) and safety specialist (CSP), 2) a microbiologist with infectious disease, bioaerosol, and medical waste expertise, 3) an environmental engineer with extensive ventilation and engineering controls experience, and 4) an environmental sampling specialist. The work was carried out over a period of two days in order that sampling data would be meaningful and reflect the variability inherent in day-to-day sampling, as well as variability in the waste stream.

Chemical Emissions. Both area and personal sampling and analyses were performed for a spectrum of environmental pollutants during the operation of the Rotoclave®. Sampling was conducted for mercury, other metals, aldehydes, volatile organic compounds (VOCs), and indoor air quality factors. None of these potential pollutants was found at or near applicable exposure limits. Mercury levels were all below the OSHA permissible exposure limit (PEL). Thirteen other metals had masses below the laboratory quantitation limit except for one sample for iron, which was well below the OSHA PEL. All 18 aldehydes tested, with the exception of formaldehyde and acrolein, were below the laboratory quantitation level. Concentrations of formaldehyde and acrolein were below the OSHA PEL. All total volatile organic compounds (VOCs) were below OSHA PELS and ACGIH TLVs. Indoor air quality monitoring was conducted during waste processing for temperature, relative humidity, carbon dioxide (CO_2) and carbon monoxide (CO). All were within acceptable limits, with CO_2 and CO well below OSHA specified limits.

Particulates and Aerosols. Total suspended particulates were collected using a standard vacuum pump method and gravimetrically measured at times ranging from 1.5 to 3 hours. All results were below the laboratory concentration detection limits which ranges between 0.033 mg/m^3 and 0.072 mg/m^3. The OSHA PEL for total particulates is 15.0 mg/m^3. Aerosols were evaluated with optical particle monitors in the exhaust stream of the waste treatment area immediately before, during, and after a Rotoclave® discharge event, and were found to be at acceptable levels.

Biological Hazards. Risks to Rotoclave® operators from biological hazards were assessed in regard to potential exposures from: 1) airborne Rotoclave® emissions during waste processing, 2) bloodborne pathogen splash and contact during waste handling, and 3) other infectious agents during waste handling and other routine operations in the waste treatment area. The Rotoclave® treatment process was evaluated for potential biological emissions by identification of potential emission points, with subsequent volumetric bioaerosol sampling and analysis during treatment cycles with and without waste spiked with bacterial indicator spores. Results showed no detection of bacterial indicator spores in any bioaerosol samples collected at potential emission points during waste treatment cycles. Bloodborne pathogen exposures were evaluated using a personal splash assessment technique, as well as surface and fluid sampling for the detection of hemoglobin as a blood marker. Results showed no personal splash exposures but testing of the operator's gloves after waste handling were positive for blood, as were fluids leaking from red bags in waste carts. A variety of waste treatment area surfaces were sampled for the presence of other infectious agents, as characterized by the presence or absence of the bacterial indicators *Escherichia coli* and *Staphylococcus aureus*. Results showed that while *E. coli* was not detected in any of 42 sites tested, *S. aureus* was isolated from 5 sites associated with surfaces in the waste treatment area, and 7 restroom control sites, indicating the presence of *S. aureus* was not unique to the waste treatment area. While these data do not indicate an infectious disease risk related directly to the Rotoclave® technology, they emphasize the need for attention to minimizing exposures related to waste handling. Potential exposures to the splashes could be significantly reduced if the hospital had made use of Tempico's automatic loader which is now part of Tempico's standard equipment offering. The demonstration of surfaces contaminated with blood and microbial agents stresses the importance of worker training, immunization, use of personal protective equipment, and personal hygiene.

Noise. Noise measurement surveys were conducted over a period of two days during Rotoclave® operation and associated activities. Daily values ranged from 76 – 84.5 dBA for Day 1, and 71.6 – 83.2 dBA for Day 2 as measured with a Sound Level Meter. Personal dosimeter readings did not exceed 81.6 dBA. These data show that operation of the Rotoclaves® during waste processing did not exceed the OSHA PEL for noise.

Engineering Controls. Engineering controls were extensively evaluated, with a major focus on ventilation and exhaust airflow during Rotoclave® operations. Air flow rate through the waste treatment facility with the bay door open as usual results in approximately 155 air

changes per hour. Evaluation of air flow and ventilation showed low levels of airborne particles and aerosols measured during waste processing. Also, the manual loading of waste into the Rotoclaves® at one facility on December 3 and 4, 1997, was observed to present potential worker risks for blood and body fluid splashes and splatters, as well as ergonomic concerns. On February 17, 1998, DynCorp performed a site visit to another Rotoclave® unit in operation in the southeastern U.S. which was equipped with the Thinline® Lift System automatic waste loader, Model # SVTL2220-2526 + 15, Bayne Machine Works, Inc., Simpsonville, SC. Results of these observations indicate that the use of the Thinline® autoloader significantly reduced the potential exposures to blood splash and splatter, biological agents, and potential injuries from sharps by eliminating the need for the operator to directly handle the red bags and sharps containers, or to lift and dump waste containers. Tempico now requires an autoloader be purchased as part of its Rotoclave® equipment offering.

General Safety. A comprehensive safety evaluation of the waste processing facility and its interface with the Rotoclave® operations was conducted over the two day period and included walk through inspection, documentation review, and interviews with waste treatment workers and facility managers. Overall, a good awareness and recognition of safety requirements was observed among Rotoclave® operators and managers. Facility management areas for training review and/or emphasis included lockout/tagout, fire alarm operation, use of personal protective equipment, and consideration of Confined Space requirements for operators needing to enter the Rotoclave® chambers.

Conclusions. A comprehensive study using environmental and personal sampling methods to identify and quantify hazards to medical waste treatment workers during operation of the Rotoclave® technology showed no metals, chemicals, particulates, or noise at or near applicable exposure limits, and confirmed the absence of potential biological emissions. Facility and management related issues were identified and focused primarily on manual waste handling and its associated risks for blood and sharps exposures, in addition to ergonomic concerns. It is recommended that all facilities using the Rotoclave® technology also use Tempico's Thinline® automatic waste loader that is now required by Tempico when purchasing the Rotoclave® technology.

1.0 CHEMICAL EMISSIONS MONITORING

Both area and personal analyses were performed for a spectrum of environmental pollutants during the operation of the Rotoclave® medical waste treatment units at the facility. Sampling was conducted for: mercury, total particulates, aldehydes, total hydrocarbons (VOCs), metals, and indoor air quality factors. These samples were collected by a Certified Industrial Hygienist (CIH) / Certified Safety Professional (CSP), over a period of two days, December 3 and 4, 1997.

1.1 Mercury. A total of seven samples were collected for analysis of concentrations of mercury. These samples were collected over a period of time ranging from approximately 2 to 4 hours. The total volume of air collected ranged from approximately 14,000 cubic centimeters of air (cc) to 34,000 cc. American Medical Laboratories (AML), located in Chantilly, Virginia provided the analysis for mercury. AML is accredited by the American Industrial Hygiene Association and participates in its proficiency testing program. See Appendix A, Table 1 for sample analysis results.

The methodology for the sampling and analysis for Mercury was NIOSH 6009. Personal and area samples were collected over a two day period. The sampling media used was SKC's Carulite sampling tubes, Lot 639, 226-17-1A. Gilian GilAir5 personal sampling pumps with a Constant Flow Low Flow Module attached to each pump was used for this sampling method. Each pump was calibrated with a Gilian Gilibrator. The pumps were calibrated to between 134.5 cc/min and 162 cc/min. The samples were analyzed using Cold Vapor Atomic Absorption (CVAA). The mercury concentration and mass results were all below the laboratory quantitation limits and the PEL for mercury which is 0.1 $mg/m^{3.}$ The laboratory concentration quantitation limits ranged from between 1.9 ug/m^3 and 4.6 ug/m^3.

1.2 Other Metals. For the analysis of metals four samples were collected. These samples were collected over a period of time ranging from approximately 2 ½ to 4 hours. The total volume of air collected ranged from approximately 320 liters to 600 liters. American Medical Laboratories (AML), located in Chantilly, Virginia provided the analysis for metals. AML is accredited by the American Industrial Hygiene Association and participates in its proficiency testing program. See Appendix A, Table 2 for sample analysis results.

The thirteen (13) metals that were analyzed for are as follows: Antimony (Sb), Beryllium (Be), Cadmium (Cd), Chromium (Cr), Cobalt (Co), Copper (Cu), Iron (Fe), Lead (Pb), Manganese (Mn), Molybdenum (Mo), Nickel (Ni), Vanadium (V), and Zinc (Zn). The methodology for the sampling and analysis for these thirteen (13) metals was NIOSH 7300 for all metals except Pb which followed NIOSH 7082. Personal samples were collected over a two day period. The sampling media that was used was 37mm Mixed Cellulose Ester Filter Cassettes, Lot A46FK. Gilian GilAir5 personal sampling pumps were used for this sampling method. Each pump was calibrated with a Gilian Gilibrator. The pumps were calibrated to between 2.66 LPM and 2.68 LPM. The samples were all analyzed using Inductively Coupled Plasma (ICP) except Pb which was used Flame Atomic Absorption (FLAA). All of the metal

samples had masses below the laboratory quantitation limit except for one Fe sample that had a mass of 0.012 mg. All of the metal samples had concentration levels below the laboratory quantitation limit except for one Fe sample that had a concentration of 0.038 mg/m^3. All results were well below their respective OSHA PEL.

1.3 Aldehydes. For the analysis of aldehyde levels, a total of six samples were collected. These samples were collected over a period of time ranging from approximately 16,000 cc to 67,500 cc. These samples were collected over a period of time ranging from approximately 1 ½ to 3 hours. The NATLSCO Laboratory, K-2, located in Long Grove, Illinois, provided the aldehyde analysis. This included the analysis for acrolein, acetaldehyde, benzaldehyde, butyradehyde, crotonaldehyde, decanal, formaldehyde, glutaraldehyde, hexaldehyde, heptaldehyde, isobutyraldehyde, isovaleraldehyde, nonanal, propionaldehyde, octylaldehyde, p-tolualdehyde, undecancal and velaraldehyde. The lab is accredited by the American Industrial Hygiene Association and participates in its proficiency testing program. See Appendix A, Table 3 for sample analysis results.

The methodology for the sampling and analysis for aldehydes was EPA IP 6. Both personal and area samples were collected over a two day period. The sampling media that was used was SKC's dinitrophenylhydrazine (DNPH) sampling tube, Lot 645, 226-119. Gilian GilAir5 personal sampling pumps with a Constant Flow Low Flow Module attached to each pump was used for this sampling method. Each pump was calibrated with a Gilian Gilibrator. The pumps were calibrated to between 297.5 cc/min and 320 cc/min. The samples were analyzed using High Performance Liquid Chromatography (HPLC). The eighteen (18) aldehydes that were analyzed for are as follows: acrolein, acetaldehyde, benzaldehyde, butyraldehyde, crotonaldehyde, decanal, formaldehyde, glutaraldehyde, hexaldehyde, heptaldehyde, isobutyraldehyde, isovaleraldehyde, nonanal, propionaldehyde, octylaldehyde, p- tolualdehyde, undecanal, and valeraldehyde. The concentration levels of all the aldehydes except formaldehyde and acrolein were all below the laboratory quantitation level. The concentration of acrolein detected ranged from 0.0086 ppm to 0.022 ppm. The concentration of formaldehyde detected ranged from below the laboratory level of detection to 0.0047 ppm. All results were well below their respective OSHA PEL and ACGIH TLV.

1.4 Volatile Organic Compounds. A total of seven samples were collected for analysis for total hydrocarbons (VOCs). These samples were collected over a period of time ranging from approximately 2 to 4 hours. The total volume of air collected ranged from approximately 15,000 cc to 34,000 cc. American Medical Laboratories (AML), located in Chantilly, Virginia provided the analysis for organic vapors. AML is accredited by the American Industrial Hygiene Association and participates in its proficiency testing program. See Appendix A, Table 4 for sample analysis results.

The methodology for the sampling and analysis for Total Hydrocarbons was OSHA 7M. Personal and area samples were collected over a two day period. The sampling media that was used was SKC's Charcoal sampling tube, Lot 2000, 226-01. Gilian GilAir5 personal sampling pumps with a Constant Flow Low Flow Module attached to each pump was used for this sampling method. Each pump was calibrated with a Gilian Gilibrator. The pumps were calibrated to between 126.5 cc/min and 156 cc/min. The samples were analyzed using Gas Chromatography, Flame Ionization Detector (GC, FID). The Total Hydrocarbon concentration levels ranged from between 0.0068 mg/m^3 and 4.48 mg/m^3. The Total Hydrocarbon mass results ranged from between 2.3 ug and 96.3 ug. All measurements for Total Hydrocarbons were below OSHA PELs and ACGIH TLVs.

2.0 PARTICULATE, AEROSOL, AND INDOOR AIR QUALITY MONITORING

2.1 Particulates. Total particulate levels were evaluated through the collection of five (5) samples. These samples were collected over a period of time ranging from approximately 1 ½ to 3 hours. The total volume of air collected ranged from approximately 140 liters to 312 liters. American Medical Laboratories (AML), located in Chantilly, Virginia provided the analysis for total dust. AML is accredited by the American Industrial Hygiene Association and participates in its proficiency testing program. See Appendix B, Table 1 for sample analysisresults.

The methodology for the sampling and analysis for Total Particulates was NIOSH 0600. Area samples were collected over a two day period. The sampling media used were pre-weighed 37mm PVC Filter cassettes, Lot PVC97-11 AML. Gilian GilAir5 personal sampling pumps were used for this sampling procedure. Each pump was calibrated using a Gilian Gilibrator. The pumps were calibrated to between 1.705 liters per minute (LPM) and 1.74 LPM. The samples were analyzed using a Gravimetric process. The particulate concentration and mass results were consistently below the laboratory concentration detection limits which ranged between 0.033 mg/m^3 and 0.072 mg/m^3. For comparison, the OSHA PEL for total particulates is 15.0 mg/m^3.

2.2 Aerosols. Aerosol measurements were made with a TSI DustTrak™ aerosol monitor that measures total mass concentration of respirable particulate, and with a Laser Particle Counter that measures the number of particles (aerosols) in various size ranges. The TSI aerosol monitor is factory calibrated to ISO 12103-1, A1 Test Dust (formerly known as Arizona Test Dust). The calculate total mass concentration from optical particle counter data, it was assumed that the average density of the particles was 1.5 g/cm^3, and that the average size for particles in the >5 micrometer range was 7 micrometers.

Aerosol measurements were made with optical instruments because these provide a real-time and simple method to obtain a large number of relatively accurate measurements of respirable particulate levels. The measurement data in this section show that the mass concentration measurements from the two instruments vary slightly. In order to precisely establish the exact mass concentrations, it would be necessary to calibrate the instruments using

high-volume sampling filters, and the actual aerosols that were being measured in the waste treatment area. However, due to the low concentrations being measured, such a calibration would be extremely time-consuming and expensive. Therefore, the instruments were used as calibrated by the respective manufacturers. It should also be noted that, because both instruments use optical methods to measure aerosol concentration, both instruments measure "steam" (condensed water vapor) concentrations, as well as solid particulate and non-water aerosols.

Aerosol measurements were made at several locations, and almost all measurements included replicates. Aerosol measurements were made at the following locations:

1) the bay door inlet to the waste treatment area,
2) at a point in front (and slightly to the side) of each Rotoclave® door, throughout a waste treatment run,
3) at a point in the operator's breathing zone, above the bottom of the waste conveyor,
4) in the exhaust air stream from the waste treatment room as a comparative control,
5) in a beach-side (non-smoking) hotel room.

The results of the aerosol measurements are summarized in Appendix B, Table 2. Aerosol concentrations in front of the Rotoclave® doors were only slightly above levels at the bay door inlet to the waste treatment area. In fact, most measurements at the facility actually had lower aerosol concentrations than were measured in a beach-side (non-smoking) hotel room for comparison.

The highest measured aerosol levels at the facility occurred during waste discharge sequences, at a point above the bottom of the waste conveyor. The measurements were made at a height roughly corresponding to the operators breathing zone, and were taken to represent what an operator would be exposed to while attempting to free a waste jam in the conveyor system (this operation was observed 2-3 times during the two days of sampling).

The measurements above the Rotoclave® waste exit chute are also shown in Appendix B, Table 2. During the December 3 measurement run, aerosol concentrations above the waste exit chute averaged 0.571 mg/m^3 for the first 3 minutes after waste was discharged from a Rotoclave®, but quickly decreased to average 0.035 mg/m^3 during the following 3 minutes (as all waste began moving up the conveyor to the shredder). This same pattern of high initial values and a rapid decrease was observed on December 4. On December 4, aerosol concentrations above the waste exit chute average 3.800 mg/m^3 for the first 4 minutes after discharge, and rapidly decreased to average 0.041 mg/m^3 during the following 2 minutes (as all waste began moving up the conveyor). The average values above the waste exit chute, even during the first 3 to 4 minutes, were substantially below the OSHA PEL of 5 mg/m^3 for respirable dust. Further, the majority of the measured aerosol levels at this point are probably due to steam release.

Aerosol concentration measurements in the exhaust stream from the waste treatment area are shown in Appendix B, Figure 1. The measurements were taken immediately before, during, and after a Rotoclave® discharge event. Appendix B, Figure 1 shows that aerosol concentrations immediately before and after the event averaged approximately 0.012 mg/m^3. As the Rotoclave® door opened and waste was discharged, levels rose to a peak of 0.180 mg/m^3, and then fell to approximately 0.030 mg/m^3, and finally dropped back to approximately 0.012 mg/m^3, when all waste was in the waste exit chute.

The average exhaust duct concentration during the 37-minute event (which included waste discharge from the Rotoclave® was 0.040 mg/m^3, or approximately 0.028 mg/m^3 above the background level. From this net concentration increase and the flow rate of 23,000 cfm, total aerosol emissions of 675 grams (1.49 pounds) can be calculated. This total aerosol emission amount can be used to evaluate how the Rotoclave® system would behave with other ventilation systems (that might not have the same high flow rate of this facility). From the relatively small total emissions of 1.49 pounds, it was found that aerosol concentrations were not a problem during operation of the Rotoclave® units.

2.3 Indoor Air Quality. The indoor air quality was evaluated by both an IAQ meter and Drager tubes. A total of six IAQ meter readings were collected for temperature, relative humidity and CO_2. A total of six direct read Drager tubes were used to collect CO results. See Appendix B, Tables 3 and 4 for sample results.

The indoor air quality was monitored using a TSI Q-Trak Indoor Air Quality (IAQ) Meter (M/N 8550) and through the use of Drager direct read tubes (DRT) Batch LC – 0581. The air was evaluated for temperature, humidity and CO_2 using the IAQ meter and for CO using the DRT. On December 3, 1997, the temperature ranged from 73.2 to 78.1 degrees Fahrenheit, the relative humidity ranged from 56.6% to 67.9%, the CO_2 levels ranged from 337 ppm to 348 ppm, and the CO levels ranged from None Detected to <2 ppm. On December 4, 1997, the temperature ranged from 73 to 75.1 degrees Fahrenheit, the relative humidity ranged from 73.7% to 77%, the CO_2 levels ranged from 290 ppm to 313 ppm, and the CO levels were all none detected. The OSHA PEL for CO_2 is 5000 ppm, and the OSHA PEL for CO is 50 ppm. Based on these data, both the CO and CO_2 levels are well below the specified OSHA limits.

3.0 BIOLOGICAL EMISSIONS AND EXPOSURE MONITORING

3.1 Biological Emissions Monitoring. Based on previous work under NIOSH a protocol to measure bioaerosol emissions in medical waste treatment facilities was developed for two purposes: 1) to measure potential worker area bioaerosol area loadings, and 2) to measure the emissions as they process spiked and non-spiked regulated medical waste.

Spiked/non-spiked waste emissions sampling are conducted at strategic locations. Spiked waste is seeded with large numbers of intrinsically chemical and heat resistant bacterial indicator spores of *Bacillus stearothermophilus* (ATCC 10149) and *Bacillus subtilis* var *globigii* (ATCC 9372). Based upon the process, the spores can be introduced into the process in a variety of ways. For the Rotoclave®, the spores are delivered dried onto membrane filters (simulating spilled, dried organisms). The indicator spores are organisms that are not expected to be common in the natural medical waste flow. The evaluation consists of monitoring bioaerosol emissions from previously identified aerosol emission points while the Rotoclave® is processing spiked and non-spiked waste. Detection of the indicator organisms would demonstrate the potential for bioaerosol emissions from the tested location or process.

Bioaerosol monitoring was conducted using samplers required or recommended in published standards and guidelines, primarily the American Society for Testing Materials (ASTM) Standard Practice for Sampling Airborne Microorganisms at Municipal Solid-Waste Processing Facilities. The bioaerosol samplers include AGI-30 all-glass impingers and Mattson/Garvin (M/G) slit-to-agar rotating plate impactor samplers.

The AGI-30s are loaded with 20 ml of sterile AOAC phosphate dilution buffer water (PBDW) and sample air at 12 liters per minutes for ten minutes. After sampling, the impinger fluid volume and a rinse with PBDW are measured and collected into a sterile container. The impinger fluid is stored on ice for transport to the DynCorp laboratory. The impinger fluid is analyzed by vortexing and plating aliquots onto duplicate plates of Trypticase Soy Agar (TSA) (BBL 4311043, Becton Dickenson and Company, Cockeysville, MD) with actidione (TSA/ac) incubated at 65°C for *B. stearothermophilus* and onto duplicate plates of TSA with actidione incubated at 35°C for *B subtilis.* The remaining impinger fluid is split with one-half filtered through a 0.2 micron membrane filter and placed on TSA/ac for incubation at 65°C for *B. stearothermophilus* and the other half filtered and placed on TSA/ac for incubation at 35°C for *B. subtilis*.

The M/G impactor samplers are run at selected locations with one containing TSA/ac for incubation at 65° C for *B. stearothermohilus* and the other for incubation at 35° C for *B. subtilis*. After sample collection the agar plates are taped closed, placed into ziplock bags, and placed into an insulated container for transport to the DynCorp laboratory for incubation and analysis.

The selected indicator organisms *B. stearothermophilus* (ATCC 10149) and *B. subtilis* var *globigii* (ATCC 9372) are initially identified by colony morphology and pigmentation.

Further laboratory tests are conducted to verify indicator organism identity. Suspected *B. stearothermophilus* colonies are subcultured onto TSA/ac for reincubation at 40°C. Growth at both temperatures is considered a positive indicator for *B. stearothermophilus*. Suspected colonies of *B. subtilis globigii* var *niger*, which appear orange on TSA with actidione, are subcultured on Tyrosine agar and incubated at 35°C. Black pigmented colonies on Tyrosine agar are a positive indicator for *B. subtilis globigii* var *niger*.

After an initial site visit and discussions with facility management and the project research team, observations indicated that there were three emission points from the Rotoclave® units that had the potential to emit microorganisms into the work area. The potential emission points were identified as: 1) at the autoclave door as the door opened post-treatment, 2) between the two Rotoclaves® as steam condensate emptied into the floor drain after a treatment cycle, and 3) at the bottom of the shredder at the point of waste impaction on the offload conveyor. The sampling scheme for both spiked and non-spiked tests at the Rotoclave® was as follows: At sampling point 1, two M/Gs and two AGI-30 impingers were placed at breathing level beside the Rotoclave® door and were started as the door opened at the end of a treatment cycle. Two consecutive 5-minute M/Gs were taken while two simultaneous 10-minute AGI-30's were taken. At sample point 2, two ten-minute AGI-30 impingers were operated at 2 to 3 feet above the drain simultaneously as the condensate drained after a treatment cycle. At sample point 3, two M/Gs and two AGI-30 impingers were placed at breathing level behind the offload conveyor at the shredded waste exit and operated as treated/shredded waste fell to the conveyor. On the first day of testing, two non-spiked tests were performed, one on each of the two Rotoclaves®. On the second day of testing, one spiked test was performed on Rotoclave® number two.

Spores of *Bacillus stearothermophilus* were purchased (ATCC 10149) and were aseptically loaded onto sterile 0.2 micron cellulose nitrate membrane filters. The filters were placed into sterile 50 x 9 mm petri dishes and dried at 40°C for two to four hours. The petri dishes were then capped and stored in zip-lock bags until testing. They were shipped to and from the facility overnight in insulated coolers. Three filters were randomly checked for spore count and viability before shipping and use in the field. Three randomly chosen filters were sent to the facility as field controls that were checked again for spore count and viability upon their return to the DynCorp laboratory. Spore suspensions as received and those eluted from the filters were quantified by performing serial dilutions in PBDW, plating onto TSA/ac, and incubating at 65°C for 24-48 hours. The average *B. stearothermophilus* spore count eluted from three filters prior to testing was 1.0×10^8 spores per filter. The average *B. stearothermophilus* spore count eluted from three filters two days after testing was 3.3×10^7 spores per filter.

Additionally, spores of *Bacillus subtilis* var *niger* (ATCC 9372) were purchased and were aseptically loaded onto sterile 0.2 micron polycarbonate and cellulose nitrate membrane filters. The filters were placed into sterile 50 x 9 mm petri dishes and dried at 40°C for two to four hours. The petri dishes were then capped and stored in zip-lock bags until testing. They were shipped to and from the facility in insulated coolers. Three filters were randomly checked for spore count and viability before shipping and use in the field. Three randomly chosen filters

were sent to the facility as field controls that were checked again for spore count and viability upon their return to the DynCorp laboratory. Spore suspensions as received and those eluted from the filters were quantified by performing serial dilutions in PBDW, plating onto TSA with actidione, and incubating at 35°C for 24 hours. The average *B. subtilis* var *niger* spore count eluted from six filters six days prior to testing was 3.3×10^8 spores per filter. The average *B. subtitis* var *niger* spore count eluted from six filters two days after testing was 8.8×10^7 spores per filter.

For the Rotoclave® spiked run, forty petri dishes with filters of *B. stearothermophilus* and forty with filters of *B. subtilis* var *niger* were placed open faced into Rotoclave® number two which had been loaded with regulated medical waste. The Rotoclave® was then operated as usual while bioaerosol monitoring was done as previously described. Results in Appendix C show no detection of bacterial indictor spores in any bioaerosol samples collected at potential emission points during waste treatment cycles.

3.2 Blood Splash Assessment. The Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29CFR 1910.1030 is to eliminate or minimize occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other blood borne pathogens. Blood borne pathogen exposure can be minimized or eliminated in a wide range of occupational settings where the potential exposure to such blood borne pathogens exist. Workers who routinely handle the collection, transport, treatment, and disposal of regulated medical waste are at risk of exposure by direct contact with blood on contaminated surfaces from spills or ruptured containers directly onto open skin cuts, abrasions, eyes, or mucous membranes, accidental needle, scalpel, or glass puncture wounds. OSHA has reported data from one medical waste company that the annual needle injury rate is 11 injuries per 1000 workers (OSHA 1991). In a survey of occupational exposure of waste industry workers to infectious waste, fifty percent of the respondents reported having received cuts and scratches, and twenty-two percent reported direct contact with waste blood (Jensen, 1995). Workers in various medical waste treatment technologies have been observed handling wastes that were leaking blood and residual fluids, resulting in blood-contamination flying through the air and landing on surfaces. These accounts indicated a need to characterize potential worker exposure to airborne blood, specifically blood splash and splatter, and blood on surfaces in the waste processing area in the medical waste treatment industry.

Under previous work for NIOSH methods were developed to assess the potential for medical waste worker exposures to blood splash and splatter and blood on surfaces. The techniques that were developed provide both visual and analytical results that verify the presence of blood.

Three test methods used are outlined below to assess worker exposure to blood splashes and splatter:

1. Blood splashes on personal protective equipment:

All procedures are performed with sterile gloves. The wiped surface area may be measured.

a) Prior to the shift, personal protective equipment (PPE)(ie. face shields, gloves, hardhats, etc.) of up to five workers are cleaned per facility protocol.

1) The PPE is then wiped with a 4" x 4" clean gauze wetted with sterile buffer.
2) The gauze is then eluted in 25 ml of sterile buffer and tested with Hemastix®.
3) The PPE is then issued to the worker.

b) After each shift.

1) Visually inspect PPE noting number and approximate size of splashes.
2) Wipe PPE with 4 x 4 inch clean gauze wetted with sterile buffer.
3) The gauze is then eluted in 25 ml of sterile buffer and tested with Hemastix ®.

c) Test extra PPE similarly as blanks by leaving them in a clean area.

2. Blood splash on clothing surfaces

This personal monitoring test uses previously developed, specifically manufactured, 4 x 4 inch NIOSH patch sample holders. The patches are loaded with clean, 4 x 4 inch cotton pads. Up to 8 patches may be installed with up to 4 on the front and up to 4 on the back of the torso. All sampling procedures are performed with sterile gloves. Workers handling regulated medical waste are monitored per shift.

a) Before each shift

1) Assemble required number of patches.
2) Attach up to 8 patches to the same relative locations of the upper body of up to five workers. Label the patches according to location.
3) Place 10° of patches in an appropriate field blank location.
4) Allow workers to work their shift.

b) At the end of each shift

1) Visually inspect patches for blood splashes. Note number or percent covered.
2) The patches and blanks are then eluted in 25 ml of sterile buffer and tested with Hemastix®.

3. Blood splashes on surfaces:

1. Identify surfaces and or protective equipment such as face shields with which workers may come in contact that could be potentially blood-contaminated.
2. While wearing clean latex gloves, open a prepared 50 ml container with 25 ml sterile FTAB solution, and moisten a 4" x 4" clean gauze.
3. Measure (when appropriate) or approximate an area and thoroughly wipe the area with the moistened gauze.
4. Place the gauze into the remainder of the 25 ml FTAB.
5. Shake vigorously for 30 seconds.
6. Test eluate with Hemastix® and record result after one minute.

A blood method quality control and method verification for the Tempico Rotoclave® study were performed as follows:

Serial dilutions from 10^{-1} through 10^{-7} of defibrinated sheep blood (Remel Labs, Lenexa, KS) were done with FTA Hemagglutination Buffer (FTAB) (Beckton Dickinson BBL11248, Cockeysville, MD). The dilution detection limit was 10^{-6}. These results are shown in Table 1. The Hemastix® literature reports a detection limit of five to twenty red blood cells (RBC) per microliter of fluid which converts to a minimum of 5 x 10^3 RBC per ml of fluid (assuming five RBC per microliter). The detection limit found experimentally can be calculated by assuming an average concentration of 5 x 10^9 RBC per ml of human blood (Campbell, 1987). In the 10^{-6} dilution, the detection limit concentration is approximately 5 x 10^3 RBC/ml which is the same as Hemastix® reports.

Table 1 Hemastix and Sheep Blood Dilution QA Test Results

Dilution[1]	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}	10^{-6}	10^{-7}
	Hemastix® - Result[2]						
Diluent Before Steam Autoclave							
FTAB	+++	+++	+++	+++	++	ht	-

1- Serial dilutions of defibrinated sheep blood were made 0.1 ml to 9.9 ml.
2- Hemastix® Test Indicator Scale: +++ Strong, ++ Moderate, +Small, ht Hemolyzed Trace, nhm Non-Hemolyzed Moderate, nht Non Hemolyzed Trace, - Negative. (One minute reading)

Results in Appendix C show no personal splash exposures but testing of the operators' gloves after waste handling were positive for blood, as were fluids leaking from red bags in waste carts.

3.3 Infectious Agent Risk. Under previous work for NIOSH, a method was developed to assess the potential for medical waste treatment worker exposure to dermal contact with infectious disease agents. The assessment is done by sampling and analysis of treatment system surfaces for human pathogen indicator organisms. Areas of treatment systems were selected that might harbor surface contamination included conveyor belts, doors and surfaces to grinding and loading mechanisms, waste carts, workers' gloves, and other surfaces in and around the treatment areas. The indicator organisms selected were *Staphylococcus aureus* and *Escherichia coli,* which are two strains of vegetative bacteria associated with human infection and/or contamination. *S. aureus* is a leading human infectious agent of skin, organs, and tissues, and is expected to be present in various types of medical waste. Its presence would indicate the potential for contamination by other virulent pathogens to include the agents of tuberculosis, pneumonia, meningitis, and others. *E. coli* is a bacterium associated with fecal contamination and is an indicator for other enteric pathogens causing serious diseases such as typhoid, dysentery, viral enteritis, and infectious hepatitis.

The field method to assess surface microbial contamination was performed as follows:

1. Identify surfaces and or protective equipment such as face shields with which workers may come in contact.
2. Aseptically moisten a sterile swab with FTAB solution.
3. Measure (when appropriate) or approximate an area and thoroughly wipe the area with the moistened swab.
4. Plate the material collected on the swab to MSA for the isolation and identification of *Staphylococcus aureus*. Another swab from an adjacent, similar area is plated onto EMB agar for the isolation and identification of *Escherichia coli.*
5. Label and record the number and location of each plate. Tape the plates closed and place them into a ziplock bag. Ship the plates in an insulated cooler for next-day delivery to the DynCorp laboratory. Incubate the plates at 35 C for 48 hours and record results.

A variety of waste treatment surface areas were sampled for the presence of infectious agents as characterized by the presence or absence of the indicator bacteria *Escherichia coli* and *Staphylococcus aureus*. Results in Appendix C showed that while *E. coli* was not detected in any of the 42 sites tested, to include control surfaces, *S. aureus* was isolated from 5 sites associated with surfaces in the waste treatment area, and 7 restroom control sites indicating the presence of *S. aureus* was not unique to the waste treatment area. While these data do not indicate an infectious disease risk related directly to the Rotoclave® technology, they once again emphasize the need for attention to minimizing exposures related to waste handling.

3.4 Quality Control for Field Blood and Microbiological Tests. The following describes reagents and quality control procedures for their use.

Microbiological Media and Reagent Preparation:

All microbiological media was prepared using DynCorp ROP Number DHSRLROP001. Media was incubated and checked for sterility prior to use. All media was checked for positive performance and growth of target organisms.

Trypticase Soy Agar with actidione (TSA/act) – DF0369, Lot #1000J9DHAT, Difco, Detroit, MI. Actidione, Lot #16H1483, Sigma Diagnostics, St. Louis, MO. Tested positive for the support of growth of *Bacillus stearothermophilus*, ATCC 10149 at 65 C and *Bacillus subtilis globigii* var *niger* at 37 C.

Tyrosine Agar – Nutrient Agar, DF0001, Lot #104916JD and L-Tyrosine, Lot #1100697JA, Difco, Detroit, MI. Tested positive for producing black colonies of *Bacillus subtilis globigii* var *niger*, ATCC 9372 at 35 C.

Mannitol Salt Agar – DF0306, Lot #1000G0DIDG, Difco, Detroit, MI. Tested positive for the support of growth of *Staphylococcus aureus*, ATCC 25923 at 37 C with positive conversion of mannitol to change the agar color from red to yellow.

Eosin Methylene Blue, Levine Agar – DF 0005, Lot #108095JS, Difco, Detroit, MI. Tested positive for the support of growth of *Escherichia coli*, ATCC 25922 at 37 C for the formation of metallic green colonies.

FTA Hemagglutination Buffer (FTAB) – B11284, Lot #1000F9D60B, Becton Dickinson, Cockeysville, MD.

Microbiological Test Organisms:

Bacillus stearothermophilus spores – ATCC 10149 – Cat# Apex Laboratories, Apex, NC.
Bacillus subtilis globigii var *niger* spores – ATCC 9372 – Apex Laboratories, Apex, NC.
Eschericia coli – ATCC 25922 – Difco Laboratories, Detroit, MI.
Staphylococcus aureus – ATCC 25923 – Difco Laboratories, Detroit, MI.

Blood Splash Reagents:

Hemastix®, Product Number 2190, Lot #7E03A, Bayer Corporation, Elkhart, IN.
Defibrinated Sheeps Blood – Cat #54-004, Lot #5651, Remel Labs, Lenexa, KS.
AOAC Phosphate Buffer Dilution Water (PBDW)

4.0 NOISE MEASUREMENT

A combination of sound level meter readings and noise dosimetry were used to evaluate noise exposure during Rotoclave® operation. A total of four (4) noise dosimeter samples were collected. On each day of sampling, a noise dosimeter was worn by the Rotoclave® Operator and a second dosimeter collected an area sample near the operator's console. The samples were collected over a period of time ranging from approximately 6 ½ to 8 hours. A total of twenty (20) sound level meter readings were collected from a variety of points throughout the Rotoclave® facility. See Appendix D, Table 1 for sample results.

The noise surveys were conducted using a Quest Sound Level Meter (SLM), (S/N H114100034) calibrated with a Quest Calibrator (M/N 2700). On December 3, 1997, the noise levels recorded by the SLM ranged from 76 dBA to 84.5 dBA and the noise levels recorded by the dosimeters were 81.6 dBA for the personal sample and 81.5 dBA for the area sample. On December 4, 1997, the noise levels recorded by the SLM ranged from 71.6 dBA to 83.2 dBA and the noise levels recorded by the dosimeters were 69.0 dBA for the personal sample and 61.45 dBA for the area sample. The Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) for noise levels is 90 dBA as an eight hour time weighted average (TWA). Based on these data, the operation of the Rotoclave® at this facility did not exceed the OSHA PEL for noise.

5.0 ENGINEERING CONTROLS

5.1Ventilation. Exhaust flow rate measurements were performed with a 36-point traverse using a standard pitot tube and magnehelic differential pressure gauge, Model 2001C AV, manufactured by Dwyer Instruments, Inc., Michigan City, IN. The pitot tube was manufactured in accordance with specifications in EPA Method 2 (40 CFR Part 60, Appendix A). The differential pressure gauge was compared with an inclined manometer (a primary standard) throughout its range prior to testing. All readings were with +/-5 percent, as required by EPA Method 2, Section 2.2.

The ventilation evaluation consisted of measurements of the total exhaust flow rate from the medical waste treatment room under varying conditions, measurements of velocities and cross-sectional areas at the inlet bay to the room, measurements of air velocities at various locations within the room, and an evaluation of the exhaust pickup locations and personnel fan locations within the room.

In Appendix E, Figure 1 shows the general layout of the room holding the two Tempico Rotoclave® units and illustrates the exhaust pickup points and air inlet locations. The room is approximately 48 feet long, 45 feet wide, and 27 feet high, and contains 3 exhaust pickups. One pickup is located directly above the waste shredder. A second pickup is located above the waste conveyor, between the two Rotoclave® units. A third pickup is located above an area of the room that occasionally holds medical waste treatment carts prior to degreasing/disinfection. All

pickups are approximately 8 feet below the room ceiling. Air enters the room primarily from two locations: the approximately 13' x 13' bay door used to remove the medical waste hauling container, and two louvered openings in the side of the building next to the bay door. These louvered openings are approximately 3' wide and 10' high. When the door next to the operator's station is opened to allow medical waste carts to enter or leave the room, air also enters this door. There are no powered supply air inlets (i.e., air enters the room due to the exhaust suction).

Appendix E, Table 1 summarizes the various ventilation measurements that were performed. The exhaust system flow rate was measured twice with the solid bay door open and once with the bay door closed. (Operators noted that the solid bay door is open nearly all the time when the Rotoclaves® are operating; it is closed only during extreme weather, such as hurricanes.) The exhaust rate was approximately 23,000 scfm with the bay door open or closed. This flow rate results in a high air exchange rate of approximately 155 air exchanges per hour within the room.

The exhaust pickup point above the shredder and the point above the waste conveyor were well-located. Steam that escaped from the shredder (despite a relatively tight-fitting rubber "curtain") appeared to be captured by the pickup directly above the shredder. The pickup point above the conveyor was located slightly behind the point at which the conveyors from the two Rotoclaves® joined. This seemed to draw the steam rising from this area slightly backward, away from the worker area, which was good. The third exhaust pickup located above the area where carts are occasionally kept prior to degreasing appeared to be unnecessary. There was no obvious source of emissions at this point during the testing period.

Due to the height of the exhaust pickups, it was not possible to measure exhaust flow rates into each pickup (only the combined flow rate from all three). All three pickup points were observed to have flow control dampers, but the exact position of the dampers could not be ascertained. It is recommended that the damper at the third pick up point (above where the carts are sometimes held) be closed, unless there is a nearby emission source that was not observed during the testing period.

Velocity measurements were made at selected points within the room. All points had acceptable velocity levels (i.e., not low enough or high enough to cause discomfort). All measurements were made with the personnel fans off. Temperatures and relative humidities within the room were essentially equal to outside temperatures and humidities on all test days (probably due to the high air exchange rate). These temperatures ranged from approximately 65-75°F, and relative humidities ranged from 60-85°. Personnel fans were generally well- placed; all fans were located such that they would provide cool fresh air if needed.

The velocity through the door where the waste carts entered was 500 ft/min. This was not a problem because the air served to open the door, the door was relatively heavy, and a piston pulled the door closed. This sort of velocity *would* be a problem if the door was oriented so that the air would tend to *close* it, because the door would tend to slam shut.

52. Waste Loading. Manual dumping of medical waste carts and medical wastes red bags as observed at the facility on December 3 and 4, 1997, presents some potential ergonomics problems with possible back strains in addition to risk of exposure from blood splashes, biological agents, and sharps injuries. It was noted by Tempico that all of the newer Rotoclave® installations are equipped with an automated waste loading system that eliminates or reduces the manual loading of waste bags.

On February 17, 1998, DynCorp performed a site visit to another Rotoclave® unit in operation in the southeastern U.S. that was equipped with the Thinline® Lift System automatic waste loader, Model # SVTL2220-2526 + 15, Bayne Machine Works, Inc., Simpsonville, SC. The purpose of the visit was to observe the operation of the automatic waste loading equipment with respect to reducing or eliminating operator exposures to blood splash and splatter, biological agents, and potential injuries from sharps.

The Rotoclave® at this facility is located outdoors under a covered loading dock attached to the hospital. The waste carts were brought to the loading dock directly from inside the hospital. Most of the waste processed by the Rotoclave® at this facility is generated by a 410 bed hospital in addition to waste that is collected from the hospitals' local laboratories and clinics. The Rotoclave® at this facility processes nominal loads of 500 pounds comprised of red bags containing pathological and laboratory wastes, and large sharps containers. The Thinline® Lift System was observed in operation for loading approximately 15 of the 1 yard bar carts as described in the Thinline® Lift System Operation Manual. The carts, whether from the hospital or from a local lab or clinic, were lined up on the loading dock. The operator wheeled each cart to a scale where the weight was recorded. Each cart was then wheeled to the autoloader. When the cart was in place on the autoloader, the operator moved to the right of the Rotoclave® and engaged the autoloader by pressing a button. The waste was transferred into the Rotoclave® while it was in the loading mode. Once all of the red bags in the cart were transferred, the autoloader lowered the waste cart and the operator wheeled the cart to a diked cleaning area adjacent to the Rotoclave® which drained directly into the sanitary sewer. One red bag was observed to fall to the loading dock floor. Per standard procedure, the operator used a long-handled wooden device that had a metal hook on the end to carefully lift the fallen bag up into the Rotoclave® unit. It was explained that future design changes to the autoloader would preclude red bags from falling. The waste carts and all spills are cleaned with a phenolic disinfectant and water. Results of these observations indicate that the use of the Thinline® autoloader significantly reduced the potential exposures from blood splash and splatter, biological agents, and potential injuries from sharps by eliminating the need for the operator to directly handle the red bags and sharps containers, or to lift anddump waste containers.

6.0 GENERAL FACILITY SAFETY EVALUATION

The safety evaluation was conducted during two full days of Rotoclave® operation. This evaluation included walk through inspection, observation, a review of documentation, and discussion with site employees and managers.

Facility management provided all facility-wide safety procedures and training programs for all hospital employees. Rotoclave® operators are included in this program. Rotoclave® operation does not have a site-specific formal training program beyond a general orientation and on the job instruction.

Overall, a good awareness and recognition of safety requirements was observed among operators and supervisors. Following this review and evaluation, several areas were noted for follow up review, and discussed with the site supervisor, as noted below.

1) Lockout/Tagout procedures need to be reviewed with operating employees. There was some uncertainty about the steps to follow during a shutdown of energized electrical systems and moving machinery.
2) Fire Extinguisher and Alarm pull positions need to be reviewed. No current tagged fire extinguisher was found in the Rotoclave® area. In addition, the only fire alarm pull station was located on the far end of the work area, near the shredder, at the maximum distance from the operator's console. In the event of a fire, it would not be realistic to expect the operator to cross this large room to sound the fire alarm.
3) The use of Personal Protective Equipment was inconsistent. Several tasks require the use of PPE to prevent splashes, cuts, or eye injury. More attention needs to be paid to the effective selection and consistent use of PPE for eye protection during compressed air blowdown in the waste loading hatch, use of thicker gloves during waste loading (latex examination gloves appear insufficient), and aprons and full body splash protection.
4) An eye wash station should be installed near the cart washing area. This is the area where chemical disinfectant and detergent solutions are sprayed onto and rinsed from the waste loading carts.
5) The interior of the Rotoclave® should be considered a Confined Space in accordance with OSHA standards. Facility operations and maintenance procedures need to recognize this classification and ensure that appropriate permitting and evaluation is conducted if entry is required.

7.0 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Chemical Emissions. Airborne chemical concentrations were determined for various VOCs, metals, and aldehydes. The medical waste as received is not chemically treated and could be expected to contain any number of trace chemicals. The analysis for total hydrocarbons (VOCs) yielded very low airborne concentration levels. The highest concentrations were the personal samples of the Rotoclave® operators, 4.48 mg/m^3 and 3.36 mg/m^3. All of the mercury results were below the laboratory quantitation limit, and therefore below the OSHA PEL. The metals analysis yielded very low concentration levels, and all were below the OSHA PELs. The aldehyde analysis yielded all results below the laboratory quantitation limit except acrolein and formaldehyde. The concentration of acrolein detected ranged from 0.0086 ppm to 0.022 ppm. The concentration of formaldehyde detected ranged from below the laboratory level of detection to 0.0047 ppm. All of these results were below their respective OSHA PELs.

The indoor air quality measurements for temperature, relative humidity, carbon monoxide (CO), and carbon dioxide (CO_2) were all within ASHRAE "Comfort Zone" criteria and applicable OSHA PELs. Only the temperature and relative humidity would be expected to demonstrate a seasonal fluctuation, with the potential for much higher readings in the summer. Although several published guidelines are available on work in Hot Environments (ACGIH, NIOSH), no OSHA standard governs this exposure.

Particulates and Aerosols. Total suspended particulates were collected using a standard vacuum pump method and gravimetrically measured at times ranging from 1.5 to 3 hours. All results were below the laboratory concentration detection limit that ranged from 0.033 mg/m^3 to 0.72 mg/m^3. The OSHA PEL for total particulates is 15.0 mg/m^3. Aerosols were evaluated with optical particle monitors in the exhaust stream of the waste treatment area immediately before, during, and after a Rotoclave® discharge event, and were found to be at acceptable levels.

Biological Hazards. Extensive testing of the Rotoclave® technology during waste processing, using bacterial indicator spores, showed no potential for emission of biological agents. Blood splash and contact exposures were evaluated and showed the potential for operator risk during waste handling. Likewise, waste handling, as opposed to the Rotoclave® operation, was identified as a risk for infectious agent transmission, as measured by a bacterial indicator organism. The demonstration of surfaces contaminated with blood and microbial agents stresses the importance of worker training, immunization, use of personal protective equipment, and personal hygiene. The use of an automated waste loading system was observed by DynCorp at a second Rotoclave® unit in operation in the southeastern U.S. The unit was equipped with the Thinline® Lift System automatic waste loader, Model #SVTL2220-2526 + 15, Bayne Machine Works, Inc., Simpsonville, SC. Results of these observations indicate that the use of the Thinline® autoloader significantly reduced the potential exposures to blood splash and splatter, biological agents, and potential injuries from sharps by eliminating the need for the operator to directly handle the red bags and sharps containers, or to lift and dump waste containers.

Noise. The noise survey of the Rotoclave® facility demonstrated that some instantaneous peak noise levels may exceed 100 dBA. The personal noise dosimeters used for this survey showed full shift TWA levels to be well below the OSHA PEL of 90 dBA. The full shift dosimetry levels were between 61.45 dBA and 81.8 dBA. Through the use of a SLM, multiple noise level readings were collected, ranging from 72 dBA to 84.5 dBA. These two days of noise surveys should be used as a gauge rather than an absolute determination of noise levels under all possible conditions. Continued periodic monitoring of noise levels should be considered, especially if conditions change.

Engineering Controls. Evaluation of existing ventilation engineering controls showed no significant ventilation problems associated with the Rotoclave® technology, so no remedial actions are necessary. Also, the use of an automated waste loading system was observed by DynCorp at a second Rotoclave® unit in operation in the southeastern U.S. The unit was equipped with the Thinline® Lift System automatic waste loader, Model # SVTL2220-2526 + 15, Bayne Machine Works, Inc., Simpsonville, SC. Results of these observations indicate that the use of the Thinline® autoloader significantly reduced the potential exposures to blood splash and splatter, biological agents, and potential injuries from sharps by eliminating the need for the operator to directly handle the red bags and sharps containers, or to lift and dump waste containers.

General Facility Safety. The operation of the Rotoclave® units at the facility received a detailed industrial hygiene and safety evaluation. All site personnel participating in this evaluation has received basic safety training and on the job orientation in the proper operation of the Rotoclave®.

Many positive observations were noted. These included minimal chemical use, only properly trained and authorized operators used the equipment, a good general awareness of the rules of operation for the equipment and the normal "routine" was closely followed. Further, all sampling results indicated exposures were well below the respective OSHA PEL for noise and airborne contaminants including metals, dust, mercury, aldehydes and volatile organic compounds.

Several suggested areas for the improvement of operator safety related to the hospital facility were noted. These suggestions were discussed with the site supervisor upon completion of the survey and included the following items:

- Ensure that appropriate Lockout/Tagout procedures are followed while working on potentially moving or energized equipment.
- Install proper fire extinguishers and alarm pulls in the operator's work area.
- Implement more consistent use of appropriate PPE.
- Install an eye wash station in the cart washing area.
- Review options to reduce potential back strains and splash exposures in waste loading such as the acquisition of the Thinline® automated cart unloading system.

Appendix A

Table 1 **Results for Mercury Analysis**

Table 2 **Results for Metals Analysis**

Table 3 **Results for Aldehyde Analysis**

Table 4 **Results for Total Hydrocarbon**

Appendix A, Table 1. Results for Mercury analysis:

Sample No.	Date	Location	Mercury Concentration	Mercury Mass
HG1	12/3/97	Area – Console	<QL*	<QL*
HG2	12/3/97	Personal – Rotoclave Operator	<QL*	<QL*
HG3	12/3/97	Area – Washing Station	<QL*	<QL*
HG4	12/3/97	Area – Rear of Conveyor	<QL*	<QL*
HG5	12/4/97	Personal – Wayne	<QL*	<QL*
HG6	12/4/97	Area – Washing Station	<QL*	<QL*
HG7	12/4/97	Personal – Butch	<QL*	<QL*
HG8	12/4/97	Blank	<QL*	<QL*

Appendix A, Table 2. Results for Metals analysis:

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
M-01	12/3/97	Rotoclave® Operator	Antimony	<0.0083 mg/m^3	0.5 mg/m^3
			Beryllium	<0.42 ug/m^3	2.0 ug/m^3
			Cadmium	<0.84 ug/m^3	5.0 ug/m^3
			Chromium	<0.0042 mg/m^3	0.5 mg/m^3
			Cobalt	<0.0042 mg/m^3	0.1 mg/m^3
			Copper	<0.0042 mg/m^3	1.0 mg/m^3
			Iron	<0.0042 mg/m^3	10.0 mg/m^3
			Lead	<8.4 ug/m^3	50.0 ug/m^3
			Manganese	<0.0042 mg/m^3	5.0 mg/m^3
			Molybdenum	<0.0084 mg/m^3	15.0 mg/m^3
			Nickel	<0.0042 mg/m^3	1.0 mg/m^3
			Vanadium	<0.0042 mg/m^3	0.5 mg/m^3
			Zinc	<0.0042 mg/m^3	5.0 mg/m^3

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
M-02	12/3/97	Rotoclave® Operator	Antimony	<0.016 mg/m^3	0.5 mg/m^3
			Beryllium	<0.78 ug/m^3	2.0 ug/m^3
			Cadmium	<1.6 ug/m^3	5.0 ug/m^3
			Chromium	<0.0078 mg/m^3	0.5 mg/m^3
			Cobalt	<0.0078 mg/m^3	0.1 mg/m^3
			Copper	<0.0078 mg/m^3	1.0 mg/m^3
			Iron	0.038 mg/m^3	10.0 mg/m^3
			Lead	<15 ug/m^3	50.0 ug/m^3
			Manganese	<0.0078 mg/m^3	5.0 mg/m^3
			Molybdenum	<0.016 mg/m^3	15.0 mg/m^3
			Nickel	<0.0078 mg/m^3	1.0 mg/m^3
			Vanadium	<0.0078 mg/m^3	0.5 mg/m^3
			Zinc	<0.0078 mg/m^3	5.0 mg/m^3

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
M-03	12/4/97	Personal - Wayne	Antimony	<0.0099 mg/m^3	0.5 mg/m^3
			Beryllium	<0.50 ug/m^3	2.0 ug/m^3
			Cadmium	<0.99 ug/m^3	5.0 ug/m^3
			Chromium	<0.0050 mg/m^3	0.5 mg/m^3
			Cobalt	<0.0050 mg/m^3	0.1 mg/m^3
			Copper	<0.0050 mg/m^3	1.0 mg/m^3
			Iron	<0.0050 mg/m^3	10.0 mg/m^3
			Lead	<9.9 ug/m^3	50.0 ug/m^3
			Manganese	<0.0050 mg/m^3	5.0 mg/m^3
			Molybdenum	<0.0099 mg/m^3	15.0 mg/m^3
			Nickel	<0.0050 mg/m^3	1.0 mg/m^3
			Vanadium	<0.0050 mg/m^3	0.5 mg/m^3
			Zinc	<0.0050 mg/m^3	5.0 mg/m^3

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
M-04	12/4/97	Personal - Butch	Antimony	<0.0089 mg/m^3	0.5 mg/m^3
			Beryllium	<0.45 ug/m^3	2.0 ug/m^3
			Cadmium	<0.89 ug/m^3	5.0 ug/m^3
			Chromium	<0.0045 mg/m^3	0.5 mg/m^3
			Cobalt	<0.0045 mg/m^3	0.1 mg/m^3
			Copper	<0.0045 mg/m^3	1.0 mg/m^3
			Iron	<0.0045 mg/m^3	10.0 mg/m^3
			Lead	<8.9 ug/m^3	50.0 ug/m^3
			Manganese	<0.0045 mg/m^3	5.0 mg/m^3
			Molybdenum	<0.0089 mg/m^3	15.0 mg/m^3
			Nickel	<0.0045 mg/m^3	1.0 mg/m^3
			Vanadium	<0.0045 mg/m^3	0.5 mg/m^3
			Zinc	<0.0045 mg/m^3	5.0 mg/m^3

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
M-05	12/4/97	Blank	Antimony	<QL*	0.5 mg/m^3
			Beryllium	<QL*	2.0 ug/m^3
			Cadmium	<QL*	5.0 ug/m^3
			Chromium	<QL*	0.5 mg/m^3
			Cobalt	<QL*	0.1 mg/m^3
			Copper	<QL*	1.0 mg/m^3
			Iron	<QL*	10.0 mg/m^3
			Lead	<QL*	50.0 ug/m^3
			Manganese	<QL*	5.0 mg/m^3
			Molybdenum	<QL*	15.0 mg/m^3
			Nickel	<QL*	1.0 mg/m^3
			Vanadium	<QL*	0.5 mg/m^3
			Zinc	<QL*	5.0 mg/m^3

Appendix A, Table 3. Results for Aldehyde analysis:

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A1	12/3/97	Area -Washing Station	Acrolein	0.107 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	0.0047 ppm	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A2	12/3/97	Area –Rear of Conveyor	Acrolein	0.015 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	0.0032 ppm	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A3	12/3/97	Wayne–Rotoclave® Operator	Acrolein	0.022 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	<QL*	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A4	12/3/97	Area – Console	Acrolein	0.014 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	0.0039 ppm	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A5	12/4/97	Area –Console	Acrolein	0.009 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	0.0026 ppm	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A6	12/4/97	Area –Behind Rotoclave®	Acrolein	0.0086 ppm	0.1 ppm
			Acetaldehyde	<QL*	200 ppm
			Benzaldehyde	<QL*	----
			Butyraldehyde	<QL*	----
			Crotonaldehyde	<QL*	2.0 ppm
			Decanal	<QL*	----
			Formaldehyde	0.0019 ppm	0.75 ppm
			Glutaraldehyde	<QL*	----
			Hexaldehyde	<QL*	----
			Heptaldehyde	<QL*	----
			Isobutyraldehyde	<QL*	----
			Isovaleraldehyde	<QL*	----
			Nonanal	<QL*	----
			Propionaldehyde	<QL*	----
			Octylaldehyde	<QL*	----
			p-Tolualdehyde	<QL*	----
			Undercanal	<QL*	----
			Valeraldehyde	<QL*	----

Sample No.	Date	Location	Analyte	Concentration	OSHA PEL
A7	12/4/97	Blank	Acrolein	None Detected	0.1 ppm
			Acetaldehyde	None Detected	200 ppm
			Benzaldehyde	None Detected	----
			Butyraldehyde	None Detected	----
			Crotonaldehyde	None Detected	2.0 ppm
			Decanal	None Detected	----
			Formaldehyde	None Detected	0.75 ppm
			Glutaraldehyde	None Detected	----
			Hexaldehyde	None Detected	----
			Heptaldehyde	None Detected	----
			Isobutyraldehyde	None Detected	----
			Isovaleraldehyde	None Detected	----
			Nonanal	None Detected	----
			Propionaldehyde	None Detected	----
			Octylaldehyde	None Detected	----
			p-Tolualdehyde	None Detected	----
			Undercanal	None Detected	----
			Valeraldehyde	None Detected	----

Appendix A, Table 4. Results for Total Hydrocarbon analysis:

Sample No.	Date	Location	Concentration	Mass
VOC1	12/3/97	Personal – Rotoclave® Operator	4.48 mg/m^3	68.6 ug
VOC2	12/3/97	Area – Console	0.39 mg/m^3	6.2 ug
VOC3	12/3/97	Area – Working Station	0.15 mg/m^3	4.0 ug
VOC4	12/3/97	Area – Rear of Conveyor	0.12 mg/m^3	3.5 ug
VOC5	12/4/97	Personal – Wayne	0.12 mg/m^3	3.0 ug
VOC6	12/4/97	Area – Workstation	0.068 mg/m^3	2.3 ug
VOC7	12/4/97	Personal – Butch	3.36 mg/m^3	96.3 ug
VOC8	12/4/97	Blank	<QL*	<QL*

Appendix B

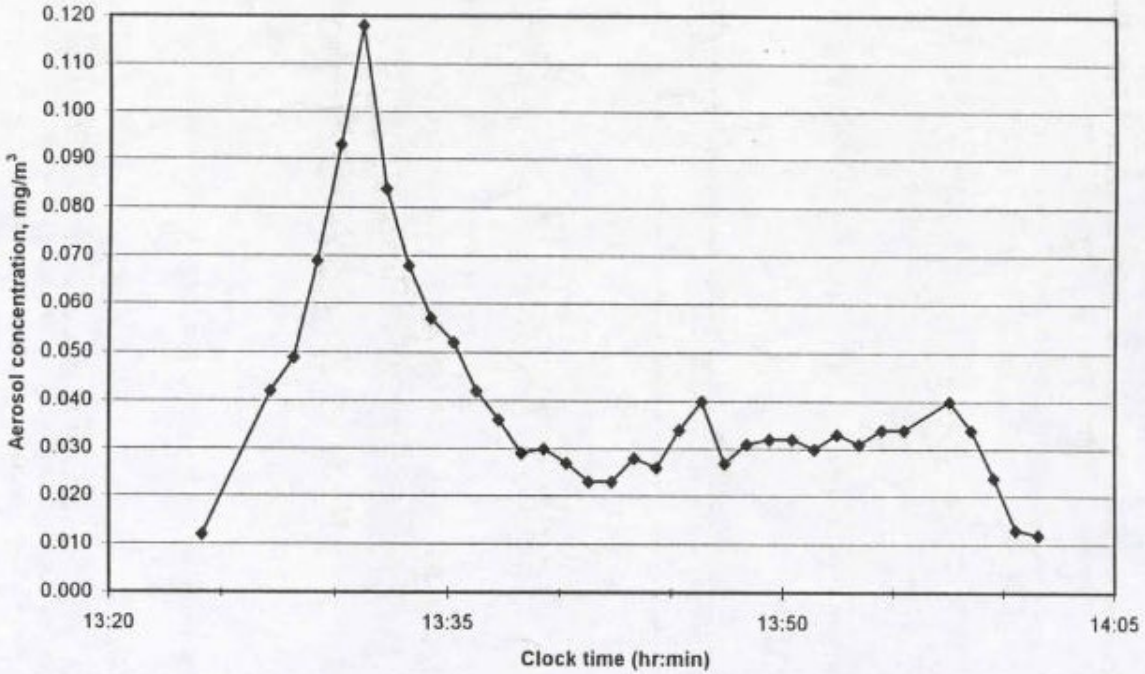
Appendix B, Table 1. Results for Total Particulates analysis:

Sample No.	Date	Location	Particulate Concentration	Particulate Mass
D1	12/3/97	Area – Rear of Conveyor	<QL*	<QL*
D2	12/3/97	Area – Rear of Conveyor	<QL*	<QL*
D3	12/3/97	Area – Rear of Conveyor	<QL*	<QL*
D4	12/4/97	Area – Console	<QL*	<QL*
D5	12/4/97	Area – Console	<QL*	<QL*
D6	12/4/97	Blank	<QL*	<QL*

Appendix B, Table 2. Aerosol concentration measurements

Measurement location and conditions	Date	Average aerosol concentration (mg/m^3)	
		By TSI Aerosol Monitor	By Optical Particle Counter
Hotel room: beach-side, non-smoking	Dec. 2	0.084	0.054*
Hotel room: beach-side, non-smoking	Dec. 3	0.060	0.072
Bay door inlet to waste treatment area	Dec. 3	0.032	0.032
Bay door inlet to waste treatment area	Dec. 4	0.016	0.021
In front of Rotoclave® (RC #1)	Dec. 3	0.036	0.050
In front of Rotoclave® (RC #2)	Dec. 3	0.033	0.028
In front of Rotoclave® (RC #2)	Dec. 4	0.017	0.031
Above waste exit chute (first 3 minutes after RC discharge)	Dec. 3	0.571	Not Measured*
Above waste exit chute (3-6 minutes after RC discharge)	Dec. 3	0.035	Not Measured*
Above waste exit chute (first 4 minutes after RC discharge)	Dec. 4	3.800	Not Measured*
(4-6 minutes after RC discharge)	Dec. 4	0.041	Not Measured

* The upper concentration limit for the optical particle counter is approximately 0.080 mg/m^3, so if particulate levels exceed this value at any time, the optical particle counter measurements will be inaccurate (biased low).



Appendix B, Figure 1. Aerosol concentrations in rotoclave room exhaust duct during discharge cycle.

Appendix B, Table 3. Results for Indoor Air Quality Meter:

Sample Date	Time	Temperature (F)	Humidity (%)	Carbon Dioxide (ppm)
12/3/97	0907	73.2	67.9	337
12/3/97	1122	75.7	60.2	348
12/3/97	1345	78.1	56.6	340
12/4/97	0851	74.2	77	311
12/4/97	1141	75.1	72.7	290
12/4/97	1444	73	74.6	313

Appendix B, Table 4: Results for Drager Direct Read Tubes for Carbon Monoxide:

Sample Date	Time	Carbon Monoxide (ppm)
12/3/97	0856	<2
12/3/97	0905	<2
12/3/97	1106	ND[1]
12/3/97	1122	ND[1]
12/3/97	1440	ND[1]
12/4/97	1215	ND[1]

[1]ND = None Detected
*QL = Laboratory Quantitation Level

Appendix C

Appendix C, Table 1. Mattson/Garvin Bioaerosol Sampling

Colony Forming Units (CFU) Recovered									
		Bacillus stearothermophilus				*Bacillus subtilis globigii* var *niger*			
		Run 1	Run 2	Run 2A[7]	Run 3	Run 1	Run 2A[7]	Run 3	Run 3
	Unit#	2	1	2	2	2	1	2	2
M/G Air Samples[1]	Date	12/3/97	12/3/97	12/3/97	12/4/97	12/3/97	12/3/97	12/3/97	12/4/97
	Rep	Non-Spiked[4]	Non-Spiked[4]	Non-Spiked[4]	Spiked[5]	Non-Spiked[4]	Non-Spiked[4]	Non-Spiked[4]	Spiked[5]
Beside Open Door[2]	-1	0	0	0	0	0	0	0	0
	-2	ND[6]	0	0	0	ND[6]	0	0	0
Offload Conveyor[3]	-1	0	0	ND[6]	0	0	0	ND[6]	0
	-2	0	0	ND[6]	0	0	0	ND[6]	0

1 – Mattson/Garvin (M/G) slit-to-agar samplers were operated at 1 cubic foot per minute. Samples were collected on Trypticase Soy Agar with actidione (TSA/act).

2 - Two M/G's were placed next to the Rotoclave® door at breathing zone height. Each was operated for two consecutive five-minute samples as the door was opened and waste was unloaded. One consecutive set was incubated at 65 C for *B. stearothermophilus,* and the second set was incubated at 35 C for *B. subtilis globigii* var *niger*.

3 – Two M/G's were placed at breathing zone height in back of the off-loading conveyor under the shredders. Each was operated for two consecutive five-minute samples for a total of ten minutes of grinding and offloading. One consecutive set was incubated at 65 C for *B. stearothermophilus* and the second set was incubated at 35 C for *B. subtilis globigii* var *niger*.

4 – The Rotoclave® was run as usual.

5 – The waste load in Rotoclave® number 2 was spiked with 40 pre-loaded 0.2 micron filters containing *B. stearothermohilus* spores, ATCC 10149 (Cat#827ST, Apex Laboratories, Apex, NC) and with 40 filters containing *B. subtilis globigii* var *niger* spores, ATCC 9372 (Cat#797GL, Apex Laboratories, Apex, NC). The average spore count/filter was 1.0×10^8 for *B. stearothermophilus*. The average spore count/filter was 3.3×10^8 for *B. subtilis globigii* var *niger*.

6 – ND = Sample not taken in the field.

7 – Run 2A was performed with M/G's only to provide a complete 10-minute sampling sequence as the door opened. This was done because the Run 1 second 5-minute samples were inadvertently omitted.

Appendix C, Table 2. Impinger Bioaerosol Sampling

Colony Forming Units (CFU) Recovered													
		Bacillus stearothermophilus						*Bacillus subtilis globigii* var *niger*					
		Run 1		Run 2		Run 3		Run 1		Run 2		Run 3	
Impinger Samples[1]	Unit#	2		1		2		2		1		2	
	Date	12/3/97		12/3/97		12/4/97		12/3/97		12/3/97		12/4/97	
	Rep	Non-Spiked[5]		Non-Spiked[5]		Spiked[6]		Non-Spiked[5]		Non-Spiked[5]		Spiked[6]	
		Plates[7]	Filter[8]	Plates[7]	Filter[8]	Plates[7]	Filter[8]	Plates[7]	Filter[8]	Plates[7]	Filter[8]	Plates[7]	Filter[8]
Beside Open Door[2]	-1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
	-2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Condensate Drain[3]	-1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
	-2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
Offload Conveyor[4]	-1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0
	-2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0

1 – All glass impingers (AGI-30) were operated at 12.5 Liters per minute.

2 – Two AGI's were placed next to the Rotoclave® door at breathing zone height. They were operated simultaneously for ten-minutes as the door was opened and waste was unloaded.

3 – Two AGI's were placed 2-feet above the condensate drain between the Rotoclaves®. They were operated simultaneously for ten-minutes after the door was opened and the condensate drain was actuated.

4 – Two AGI's were placed at breathing zone height in back of the off-loading conveyor under the shredders. They were operated simultaneously for ten-minutes during grinding and offloading.

5 – The Rotoclave® was run as usual.

6 – The waste load in Rotoclave® number 2 was spiked with 40 pre-loaded 0.2 micron filters containing *B. stearothermophilus* spores. ATCC 10149 (Cat #827ST, Apex Laboratories, Apex, NC) and with 40 filters containing *B. subtilis globigii* var *niger* spores, ATCC 9372 (Cat #797GL, Apex Laboratories, Apex, NC) The average spore count/filter was 1.0×10^8 for *B. stearothermophilus*. The average spore count/filter was 3.3×10^8 for *B. subtilis globigii* var *niger*.

7 – Number of indicator organism CFU isolated from duplicate 0.1 mL impinger fluid plated onto Trypticase Soy Agar with actidione (TSA/act). Two from each impinger were incubated at 65 C for *B. stearothermophilus* and two were incubated at 35 C for *B. subtilis globigii* var *niger*

8 - Number of indicator organism CFU isolated from filtering half of the remaining impinger was incubated at 65 C for *B. stearothermophilus* and one was incubated at 35 C for *B. subtilis globigii* var *niger.*

Appendix C, Table 3. Blood Splash and Splatter – Personal Sampling

Sample #	Date	Sampling Location / Description	Area	Hemastix Result	Comment
1	12/3/97	Patch #1-Front torso, upper right – After shift[1]	4"x4"	Neg	Slightly soiled
2	12/3/97	Patch #2-Front torso, upper left – After shift[1]	4"x4"	Neg	No visible blood/fluids
3	12/3/97	Patch #3-Front torso, lower right – After shift[1]	4"x4"	Neg	Slightly soiled
4	12/3/97	Patch #4-Front torso, lower left – After shift[1]	4"x4"	Neg	No visible blood/fluids
5	12/3/97	Patch #5-Back torso, upper left – After shift[1]	4"x4"	Neg	No visible blood/fluids
6	12/3/97	Patch #6-Back torso, upper right – After shift[1]	4"x4"	Neg	No visible blood/fluids
7	12/3/07	Latex gloves before waste handling[2]	Entire	Neg	No visible blood/fluids
8	12/3/97	Latex gloves after waste handling[2]	Entire	Neg	No visible blood/fluids
9	12/3/97	Latex gloves before waste handling[2]	Entire	Neg	No visible blood/fluids
10	12/3/97	Latex gloves after waste handling[2]	Entire	++	No visible blood/fluids
11	12/3/97	Latex gloves before waste handling[2]	Entire	Neg	No visible blood/fluids
12	12/3/97	Latex gloves after waste handling[2]	Entire	Neg	1" Tear exposing skin-left hand
13	12/3/97	Faceshield[3]	Entire	Neg	No visible blood/fluids
14	12/3/97	Neg control[4]		Neg	Control
15	12/3/97	Pos control[5]		+++	Control
16	12/4/97	Patch #1-Front torso, upper right – After shift[1]	4"x4"	Neg	No visible blood/fluids
17	12/4/97	Patch #2-Front torso, upper left – After shift[1]	4"x4"	Neg	No visible blood/fluids
18	12/4/97	Patch #3-Front torso, lower right – After shift[1]	4"x4"	Neg	No visible blood/fluids
19	12/4/97	Patch #4-Front torso, lower left – After shift[1]	4"x4"	Neg	No visible blood/fluids
20	12/4/97	Patch #5-Back torso, upper left – After shift[1]	4"x4"	Neg	No visible blood/fluids
21	12/4/97	Patch #6-Back torso, upper right – After shift[1]	4"x4"	Neg	No visible blood/fluids
22	12/4/97	Latex gloves after waste handling[2]	Entire	+Ht	No visible blood/fluids
23	12/4/97	Latex gloves before waste handling[2]	Entire	Neg	No visible blood/fluids
24	12/4/97	Latex gloves after waste handling/cart wash[2]	Entire	Neg	No visible blood/fluids
25	12/4/97	Latex gloves before waste handling[2]	Entire	Neg	No visible blood/fluids
26	12/4/97	Latex gloves after waste handling[2]	Entire	Neg	No visible blood/fluids
27	12/4/97	Neg control[4]		Neg	Control
28	12/4/97	Pos control[5]		+++	Control

1 - A 4" x 4" cotton pad was attached to the workers' apron. The pads were worn throughout the shift as waste was processed. At the end of the shift, each patch was removed and eluted into a tube containing 25 mL of sterile AOAC phosphate dilution buffer water (PBDW). The patch was shaken in the buffer for 30 seconds and the eluate was tested with a Hemastix® (Product 2190, Bayer Corp., Elkhart, IN. Lot# 7E03A).

2 – A clean cotton swab was moistened with PBDW and both gloves were wiped. The cotton was eluted in 25 mL PBDW and tested with a Hemastix®.

3 – A clean cotton swab was moistened with PBDW, and the entire face shield was wiped. The cotton was eluted in 25 mL PBDW and tested with a Hemastix®.

4 – Unused PBDW was tested with a Hemastix®.

5 – A serial dilution of 1:10000 defibrinated sheep's blood (Cat #54-004, Lot# 5651, Remel Labs, Lenexa, KS) was tested as a positive control.

Appendix C, Table 4. Blood Splash and Splatter – Surface Sampling

Sample #	Date	Sampling Location / Description[1]	Area	Hemastix Result	Comment
1	12/3/97	Leaking fluid from waste – bottom cart#1	Dip	Neg	Clear liquid
2	12/3/97	Leaking fluid from waste – bottom cart#2	Dip	+++	Red tinted liquid
3	12/3/97	Leaking fluid from waste – bottom cart#2	Dip	+++	Clear liquid
4	12/3/97	Leaking fluid from waste – bottom bin	Dip	Neg	Milky liquid
5	12/3/97	Interior waste exit chute – Roto#1	6”x6”	Neg	
6	12/3/97	Interior waste conveyor drain pan – Roto#1	6”x6”	+	No visible blood
7	12/3/97	Small broom handle	Entire	Neg	
8	12/3/97	Interior waste exit chute – Roto#2	6”x6”	Neg	
9	12/3/97	Interior waste conveyor drain pan – Roto#2	6”x6”	+	No visible blood
10	12/3/97	Control panel touch pads (both)	Entire	Neg	
11	12/3/97	Door panel	6”x6”	Neg	
12	12/3/97	1L-NDP Power supply panel	6”x6”	Neg	
13	12/3/97	Top/CP4box, Roto#1	6”x6”	Neg	
14	12/3/97	Top/CP5 box, Roto#2	6”x6”	Neg	
15	12/3/97	Top wooden file cabinet near shredder	6”x6”	Neg	
16	12/3/97	Telephone	Entire	Neg	
17	12/3/97	Door handle	Entire	Neg	
18	12/3/97	Exterior waste exit chute, Roto #1	6”x6”	Neg	
19	12/3/97	Exterior waste exit chute, Roto #2	6”x6”	Neg	
20	12/3/97	Large push broom handle	Entire	Neg	
21	12/3/97	Positive Control[2]	Dip	+++	Control
22	12/3/97	Negative Control[3]	Dip	Neg	Control

1 – A 4” x 4” cotton pad was wetted with sterile AOAC phosphate dilution buffer water (PBDW) and wiped over described surface. The pad was then eluted into a tube containing 25 mL of sterile PBDW by shaking for 30-seconds and the eluate was tested with a Hemastix® (Product 2190, Bayer Corp., Elkhart, IN. Lot# 7E03A).

2 – A serial dilution of 1:10000 defibrinated sheep’s blood (Cat# 54-004, Lot#5651, Remel Labs, Lenexa, KS) was tested as a positive control.

3 – Unused PBDW was tested as a negative control.

4 – Tub cleaning fluids were tested for possible reaction with the Hemastix® and were found to be negative.

Appendix C Table 4. Blood Splash and Splatter – Surface Sampling (Continued)

Sample #	Date	Sampling Location / Description[1]	Area	Hemastix Result	Comment
23	12/4/97	Inside waste cart #1	6”x6”	Neg	
24	12/4/97	Inside waste cart #2	6”x6”	Neg	
25	12/4/97	Inside waste cart #3	6”x6”	Neg	
26	12/4/97	Leaking fluid from waste – Bottom cart#1	Dip	Neg	
27	12/4/97	Leaking fluid from waste – Bottom cart#2	Dip	+	Clear liquids
28	12/4/97	Leaking fluid from waste – Bottom cart#3	Dip	+++	Clear liquids
29	12/4/97	Leaking fluid from waste – Bottom cart#4	Dip	+++	Clear liquids
30	12/4/97	Leaking fluid from waste – Bottom cart#5	Dip	+++	Clear liquids
31	12/4/97	Leaking fluid from waste – Bottom cart#6	Dip	Neg	
32	12/4/97	Leaking fluid from waste – Bottom cart#7	Dip	Neg	
33	12/4/97	Interior waste exit chute – Roto#1	6”x6”	Neg	
34	12/4/97	Exterior waste exit chute – Roto#1	6”x6”	Neg	
35	12/4/97	Degreaser – Control[4]	Dip	Neg	
36	12/4/97	Disinfectant – Control[4]	Dip	Neg	
37	12/4/97	Interior waste exit chute – Roto #2	6”x6”	+++	No visible blood
38	12/4/97	Exterior waste exit chute – Roto #2	6”x6”	++	No visible blood
39	12/4/97	Control panel touchpads (both)	Entire	Neg	
40	12/4/97	Control panel buttons (all)	Entire	Neg	
41	12/4/97	Door handle	Entire	Neg	
42	12/4/97	Small broom handle	Entire	Neg	
43	12/4/97	Large push broom handle	Entire	Neg	
44	12/4/97	Positive control[2]	Dip	+++	Control
45	12/4/97	Negative control[3]	Dip	Neg	Control

1 – A 4”x4” cotton pad was wetted with sterile AOAC phosphate dilution buffer water (PBDW) and wiped over the described surface. The pad was then eluted into a tube containing 25 mL of sterile PBDW by shaking for 30-seconds and the eluate was tested with a Hemastix® (Product 2190, Bayer Corp., Elkhart, IN. Lot #7E03A).

2 – A serial dilution of 1:10000 defibrinated sheep’s blood (Cat# 54-004, Lot#5651, Remel Labs, Lenexa, KS) was tested as a positive control.

3 – Unused PBDW was tested as a negative control.

4 – Tub cleaning fluids were tested for possible reaction with the Hemastix® and were found to be negative.

Appendix C, Table 5. Surface Microbial Sampling for *S. aureus*.

Sample #	Date	Sampling Location[1]	Area	Total CFU	Total *S. aureus*
1	12/3/97	Bottom waste container (clear fluid)	2”x2”	64	23
2	12/3/97	Interior surface of unload chute – Roto #1	2”x2”	106	0
3	12/3/97	Interior surface of unload chute – Roto #2	2”x2”	TNTC	TNTC
4	12/3/97	½ Control panel touch pad – Roto #1		TNTC	0
5	12/3/97	½ Control panel touch pad – Roto #2		38	0
6	12/3/97	Entire face shield at wash station		42	0
7	12/3/97	Wash station back wall	2”x2”	0	0
8	12/3/97	Faucet handles – sink next to door		51	0
9	12/3/97	Conveyor drain pan – Roto #1	2”x2”	29	0
10	12/3/97	Conveyor drain pan – Roto #2	2”x2”	TNTC	0
11	12/3/97	All buttons on control panel		TNTC	0
12	12/3/97	Inside door handle next to sink		84	80
13	12/3/97	Conveyor drain pan – Center	2”x2”	TNTC	0
14	12/3/97	Telephone		0	0
15	12/3/97	Hose nozzle at wash station	1”x6”	0	0
16	12/3/97	Biohazard waste bin top – next to sink	2”x2”	18	0
17	12/3/97	Control – Toilet seat, men’s room	2”x2”	TNTC	TNTC
18	12/3/97	Control – Inside rim of toilet, men’s room	2”x2”	27	25
19	12/3/97	Control – Toilet handle	2”x2”	215	15
20	12/3/97	Control – Sink faucet handles		167	167
21	12/3/97	Field blank	N/A	0	0
22	12/4/97	Control – Toilet seat, men’s room	2”x2”	52	20
23	12/4/97	Control – Inside rim of toilet, men’s room	2”x2”	0	0
24	12/4/97	Control – Toilet handle, men’s room	2”x2”	24	1
25	12/4/97	Control – Sink faucet handles, men’s room		89	53
26	12/4/97	Inside waste cart #1	2”x2”	TNTC	25
27	12/4/97	Inside waste cart #2	2”x2”	0	0
28	12/4/97	Inside waste cart #3	2”x2”	23	3
29	12/4/97	Inside waste cart #4	2”x2”	TNTC	0
30	12/4/97	Inside waste cart #5	2”x2”	0	0
31	12/4/97	Inside waste cart #6	2”x2”	93	61
32	12/4/97	Inside waste cart #7	2”x2”	256	0
33	12/4/97	Interior surface of unload chute – Roto #1	2”x2”	33	0
34	12/4/97	Exterior surface of unload chute – Roto #1	2”x2”	12	0
35	12/4/97	Interior surface of unload chute – Roto #2	2”x2”	47	0
36	12/4/97	Exterior surface of unload chute – Roto #2	2”x2”	3	0
37	12/4/97	Cntrl panel sfc between touchpad and buttons		33	0
38	12/4/97	Faucet handles – sink next to door		8	0
39	12/4/97	Conveyor drain pan – Roto #1	2”x2”	59	0
40	12/4/97	Conveyor drain pan – Center	2”x2”	TNTC	0
41	12/4/97	Conveyor drain pan – Roto #2	2”x2”	TNTC	0
42	12/4/97	Bay door open/close button		15	0

1 – Sterile swabs were moistened with FTAB buffer and wiped over the indicated surface. The swab was then plated onto Mannitol Salt Agar and incubated at 37 C for 48 hrs.

Appendix C, Table 6. Surface Microbial Sampling for *E. Coli*.

Sample #	Date	Sampling Location[1]	Area	Total CFU	Total *S. aureus*
1	12/3/97	Bottom waste container (clear fluid)	2”x2”	TNTC	0
2	12/3/97	Interior surface of unload chute – Roto #1	2”x2”	TNTC	0
3	12/3/97	Interior surface of unload chute – Roto #2	2”x2”	TNTC	0
4	12/3/97	½ Control panel touch pad – Roto #1		TNTC	0
5	12/3/97	½ Control panel touch pad – Roto #2		TNTC	0
6	12/3/97	Entire face shield at wash station		TNTC	0
7	12/3/97	Wash station back wall	2”x2”	0	0
8	12/3/97	Faucet handles – sink next to door		TNTC	0
9	12/3/97	Conveyor drain pan – Roto #1	2”x2”	TNTC	0
10	12/3/97	Conveyor drain pan – Roto #2	2”x2”	TNTC	0
11	12/3/97	All buttons on control panel		0	0
12	12/3/97	Inside door handle next to sink		0	0
13	12/3/97	Conveyor drain pan – Center	2”x2”	TNTC	0
14	12/3/97	Telephone		0	0
15	12/3/97	Hose nozzle at wash station	1”x6”	0	0
16	12/3/97	Biohazard waste bin top – next to sink	2”x2”	TNTC	0
17	12/3/97	Control – Toilet seat, men’s room	2”x2”	0	0
18	12/3/97	Control – Inside rim of toilet, men’s room	2”x2”	0	0
19	12/3/97	Control – Toilet handle	2”x2”	0	0
20	12/3/97	Control – Sink faucet handles		0	0
21	12/3/97	Field blank	N/A	0	0
22	12/4/97	Control – Toilet seat, men’s room	2”x2”	0	0
23	12/4/97	Control – Inside rim of toilet, men’s room	2”x2”	0	0
24	12/4/97	Control – Toilet handle, men’s room	2”x2”	0	0
25	12/4/97	Control – Sink faucet handles, men’s room		0	0
26	12/4/97	Inside waste cart #1	2”x2”	TNTC	0
27	12/4/97	Inside waste cart #2	2”x2”	0	0
28	12/4/97	Inside waste cart #3	2”x2”	0	0
29	12/4/97	Inside waste cart #4	2”x2”	TNTC	0
30	12/4/97	Inside waste cart #5	2”x2”	0	0
31	12/4/97	Inside waste cart #6	2”x2”	0	0
32	12/4/97	Inside waste cart #7	2”x2”	TNTC	0
33	12/4/97	Interior surface of unload chute – Roto #1	2”x2”	0	0
34	12/4/97	Exterior surface of unload chute – Roto #1	2”x2”	0	0
35	12/4/97	Interior surface of unload chute – Roto #2	2”x2”	0	0
36	12/4/97	Exterior surface of unload chute – Roto #2	2”x2”	0	0
37	12/4/97	Cntrl panel sfc between touchpad and buttons		TNTC	0
38	12/4/97	Faucet handles – sink next to door		0	0
39	12/4/97	Conveyor drain pan – Roto #1	2”x2”	TNTC	0
40	12/4/97	Conveyor drain pan – Center	2”x2”	TNTC	0
41	12/4/97	Conveyor drain pan – Roto #2	2”x2”	TNTC	0
42	12/4/97	Bay door open/close button		0	0

1 – Sterile swabs were moistened with FTAB buffer and wiped over the indicated surface.
The swab was then plated onto Eosin Methylene Blue, Levine Agar and incubated at 37 C for 48 hrs.

Appendix D

Table 1 Results for Noise Dosimeter

Appendix D, Table 1. Results for Noise Dosimeter:

	12/3/97	12/3/97	12/4/97	12/4/97
	Personal – Wayne	Area – Console	Personal – Wayne	Area - Console
Runtime	5 hr 46 min	7 hr 13 min	7 hr 8 min	7 hr 6 min
Average Level	81.6 dBA	81.5 dBA	69.0 dBA	61.45 dBA
Maximum Level	----	108 dBA	113.8 dBA	100.8 dBA
% Dose	22.60%	4.00%	5.70%	3.90%

Appendix E

Figure 1 **Floor Plan**

Table 1 **Ventilation Measurements**

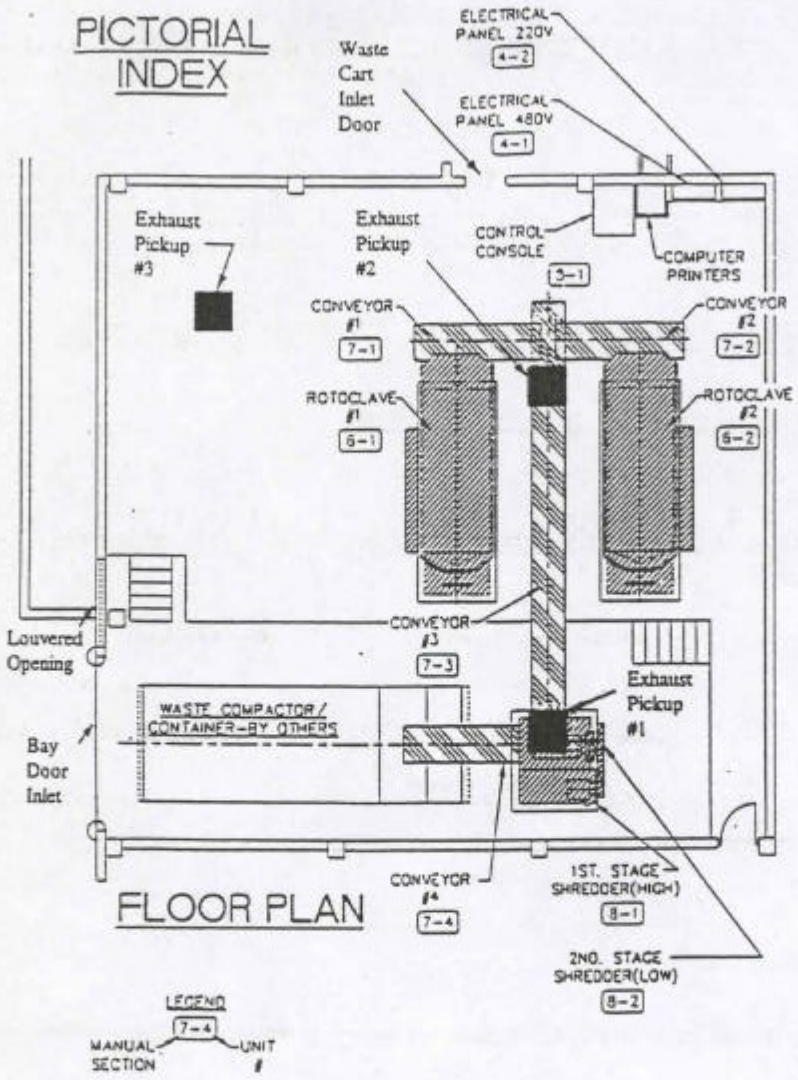


Figure 1. Floor plan for rotoclave room, with exhaust pickup points and room air inlet locations.

Tempico Rotoclave Medical Products, Inc.

Appendix E, Table 1. Ventilation Measurements

Measurement	Value
Exhaust rate from room (bay door open, traverse #1)	23,000 cfm
Exhaust rate from room (bay door open, traverse #2)	21,900 cfm
Exhaust rate from room (bay door closed)	23,000 cfm
Air exchange rate	155 air changes per hour
Velocity measurements	
At operator station	25 ft/min
At sampling area in front of Rotoclaves®	65 ft/min
At bay door, and at louvered inlet (with bay door open)	75 ft/min, 200 ft/min
At louvered inlet (with bay door closed)	550 ft/min
At waste inlet door to Rotoclave® room (door open)	500 ft/min