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Stericycle, Inc.
Morton, Washington

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PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the workplace. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer or authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

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Health Hazard Evaluation Report 98-0027-2709
Stericycle, Inc.
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October 1998

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SUMMARY

At the request of Washington State's Department of Labor and Industries (L&I) and Department of Health (DOH), the National Institute for Occupational Safety and Health (NIOSH) evaluated the potential for occupational exposures to *Mycobacterium tuberculosis* (Mtb) and bloodborne pathogens from the processing of medical waste at Stericycle, Inc. in Morton, Washington. Events leading to this request for technical assistance included an outbreak of suspected occupationally-related tuberculosis (TB) among employees at Stericycle. An initial site visit was conducted November 18-20, 1997, and a subsequent evaluation of the facility was performed January 26-29, 1998. The information contained in this report reflects conditions at the facility at the time of these evaluations. An interim report, including initial recommendations, was distributed on March 13, 1998.

During the medical evaluation, NIOSH investigators interviewed employees, reviewed available medical records, and reviewed the Occupational Safety and Health Administration (OSHA) log and summary of occupational injuries and illnesses (form 200) for the years 1992-1997. NIOSH also met with representatives from the Division of TB Elimination (DTBE)/Centers for Disease Control and Prevention (CDC) and from the Washington State DOH to discuss the Washington State DOH's epidemiologic investigation of three active cases of TB among Stericycle employees.

Employee interviews revealed misconceptions among employees regarding the seriousness of needlestick and other sharp object injuries, and of splashes to the eyes, nose, mouth, or skin. Employees also reported uncertainty about the correct way to put on and remove protective clothing and equipment. A medical records review revealed deficiencies in medical evaluations concerning prophylactic as well as follow-up care of potential exposures to Mtb and bloodborne pathogens. Review of the OSHA 200 logs revealed differences in reported needlestick injuries and records of follow-up care for these injuries.

The environmental evaluation consisted of observation of work practices and review of work and safety policies and procedures. A variety of environmental sampling methods was utilized to assess the potential for aerosolization of components from the medical waste stream. Methods included the following: theatrical smoke was released to visualize airflow patterns throughout the plant; tracer gas was used to identify potential leaks from the process; pressure sensors were used to quantify relative pressure between areas of the plant; flourescein dye solution was used to spike waste being processed, during which time air samples were collected and later analyzed for the presence of the dye; and bioaerosol samples were collected to evaluate the presence of aerosolized organisms associated with medical waste (*Escherichia coli, Pseudomonas aeruginosa*, and *Staphylococcus aureus*). Factors identified during the course of the evaluation which may have contributed to employees' potential exposures to Mtb and bloodborne pathogens included deficiencies in the operation, maintenance, and storage of

respiratory protection equipment used in the containment area; use of an airline respirator system that did not meet NIOSH approval; lack of availability of an appropriately designed change room for the employees exiting the containment room; and training programs that did not provide employees with sufficient information regarding decontamination procedures. In addition, company policies were not always followed, resulting in operation of the processing system without particulate filters in place and cleaning of filters with compressed air.

Employees reported that a situation referred to as "blowback" frequently occurred, i.e., the air from the containment room would blow back out of the in-feed chute into the main plant area when the shredders became clogged. NIOSH documented such an event during the evaluation. Additionally, work practices required to unclog processing shredders put employees in direct contact with needles and other sharp objects.

Flourescein dye was present on two of the air samples collected at the in-feed station, indicating the potential for aerosolizing waste materials. In addition, visible smoke patterns revealed the potential for small quantities of air to overcome the capture velocity at the face of the in-feed chute. Although the ventilation at the in-feed chute usually appeared to be adequate, there were two situations of concern: during dumping of waste from the Steritubs into the in-feed chute and when the process line became clogged. An additional concern involved the re-entrainment of exhaust air from the containment room, since leak testing had not been performed on the high efficiency particulate air (HEPA) exhaust filters since the time of installation in January 1992.

An epidemiologic investigation performed by the Washington State DOH included drug susceptibility testing which showed that the three cases of active TB among employees at the Morton facility each had a different susceptibility pattern, thus eliminating the possibility of person-to-person transmission between these three employees. A contact investigation identified no other person-to-person sources of infection for these three cases. According to a DOH press release, further laboratory testing confirmed that one of the cases was infected with a strain of Mtb identical to the strain identified in a person treated at a facility that sends waste to Stericycle.

NIOSH identified several factors present in the Morton facility that could contribute to employee exposures to pathogens potentially present in the medical waste. These included the use of a process that creates the potential for aerosolization of the products contained in the waste prior to deactivation; deficiencies in the design of the facility; the policies in place at the facility; the design and operation of the equipment used at the facility (including personal protective equipment); and misunderstandings among employees about operations, personal protective equipment, medical issues, and policies and procedures. Recommendations to help prevent exposures to Mtb and bloodborne pathogens are provided at the end of this report.

Keywords: Tuberculosis, TB, *Mycobacterium tuberculosis*, medical waste, medical waste treatment, infectious waste.

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INTRODUCTION

At the request of Washington State's Department of Labor and Industries (L&I) and Department of Health (DOH), the National Institute for Occupational Safety and Health (NIOSH) evaluated the potential for occupational exposures to *Mycobacterium tuberculosis* (Mtb) and bloodborne pathogens from the processing of medical waste. Events leading to the request for technical assistance included an outbreak of suspected occupationally-related tuberculosis (TB) among employees at Stericycle, Inc. in Morton, Washington. An initial site visit was conducted November 18-20, 1997, and a subsequent evaluation of the facility was performed January 26-29, 1998. The information contained in this report reflects conditions at the facility at the time of these evaluations. An interim report, including initial recommendations, was distributed on March 13, 1998.

BACKGROUND

Process Description

Stericycle, Inc. has developed and employs an alternative treatment technology which is designed to deactivate medical waste by a heating process referred to as electrothermal deactivation (ETD)™.[1] The process reportedly uses low frequency (64 MHZ) radiation with 15-foot wavelengths and an electrical field strength of 50,000 volts per meter. The material to be heated is placed in the electrical field between two parallel plates or electrodes where it becomes the dielectric of a capacitor. Electrical energy is transferred directly to the waste, which causes the polar molecules to rotate rapidly in synchronization with the electrical field. Operating parameters for the dielectric heater (e.g., field strength, conveyor speed, dwell time of the waste in the unit) are preset and controlled by a programmable logic circuit. The radio-frequency (RF) operator is responsible for ensuring that all parameters are met. Stericycle ETD facilities are presently operating in Morton, Washington; Woonsocket, Rhode Island; Yorkville, Wisconsin; Loma Linda, California; and Toluca, Mexico. Stericycle also recently announced plans to establish their ETD technology in Sao Paulo, Brazil (Stericycle, Inc. PR Newswire, July 28, 1998).

The RF heating system (oven) was purchased from Process Heating Solutions (PSC), Inc. of Cleveland, Ohio. Traditional dielectric applications include processing (drying) textiles, plastics, ceramics, rubber, wood, food, and other nonconducting materials. A site visit to the PSC facility was conducted by NIOSH on July 30, 1998, to learn more about the construction, operating parameters, advantages, and limitations of the ovens. PSC, Inc. makes no claims as to the effectiveness of their oven in deactivating infectious medical waste; they only state that their oven is designed to heat materials to a specified temperature.

Stericycle's medical waste processing facility in Morton, Washington, began operating in January 1992. The facility receives waste from clinical laboratories, hospitals, and medical and dental clinics (collectively referred to as Stericycle's "customers") located in Washington, Idaho, Oregon, and British Columbia. The types of waste which are processed consist of cultures and stocks of infectious agents and associated biologicals; liquid human waste, including blood, blood products, and body fluids; sharps; isolation wastes; and small amounts of human pathological waste if mixed with other categories of biomedical waste. Waste which is not accepted by Stericycle includes chemotherapeutic waste, residually-contaminated chemotherapeutic waste, pathological and anatomical waste (except as noted above), chemicals, and radioactive waste.

The processing plant consists of a 13,500-square-foot area with an 800 square-foot, two-story steel-walled containment room located in the center of the plant floor. The containment area consists of (1) a change room where employees don protective equipment before entering the containment and de-gown after exiting the containment, (2) a press room where processed waste is compacted into vessels prior to entering the RF oven, and (3) a "pit area" where processing equipment (i.e., shredders, filters,

conveyors, etc.) is located. A floor plan of the facility is shown in Figure 1 (not to scale).

Medical waste is transported to the facility in either 24- or 48-foot trailers (drivers are Stericycle employees). Incoming infectious waste is received in either plastic containers with snap-on lids (referred to as Steritubs®) or cardboard boxes (which contain anatomical waste). Truck unloaders are responsible for unloading Steritubs and boxes from the trailers by placing them on a hand truck and transporting them to a powered conveyor leading to the in-feed station. Unloaders are also responsible for general housekeeping in the tub wash area and sanitizing the empty trailers. At the in-feed station, the feed system operator weighs the containers; a scanner is located at the in-feed station which reportedly detects the presence of hydrocarbons and radioactive materials in the waste (the scanner was not evaluated by NIOSH as part of this investigation). Cardboard boxes containing anatomical waste are placed in a cooler to be transported later to an incinerator. According to Stericycle representatives, anatomical waste makes up about 3 % of the total volume of waste received at the Morton facility.

Lids from the Steritubs are removed, and the contents are manually dumped into the processing unit via an in-feed chute. The feed system operator is responsible for unclogging the system. This requires entering the containment area on a daily basis to access the primary and secondary shredders in the pit. Once emptied, Steritubs are conveyed to the tub wash station where they are removed from the conveyor and placed upside down over a pressure wash nozzle while employees (two per shift) scrub the outside of the tub with a sponge. At the wash station, tubs are sanitized with hot water (maintained at 180°F) and a mild surfactant. The water used in the tub wash station is recycled and used to wet shredded waste inside the containment room. Once washed, containers are sent through a drier and placed on trailers to be sent back to Stericycle customers.

After the waste has been dumped into the in-feed chute, it travels through the chute which drops 8 feet to the primary shredder located on the floor of the pit. Waste is initially shredded to small fragments averaging about four to eight inches in greatest diameter. The chute directs the waste to a secondary shredder, which further reduces the waste in a multi-stage process, to pieces less than 3/8 inch in diameter.

A conveyor transfers the shredded waste up to the press room, where it is discharged into 23-cubic foot polyethylene process vessels at the fill station. The press operator compacts the infectious waste in the vessel to an average density of 25 pounds per cubic foot and an approximate weight of 500 pounds. While the waste is being compacted, the operator is responsible for distributing the shredded waste uniformly throughout the vessel and for spraying the waste with water to achieve a 10 to 15 % moisture content (moisture content is not monitored). The waste takes approximately 8 to 10 seconds to travel from the in-feed station to the processing vessel. The shredding and compacting process is carried out in an enclosed area which is under negative pressure. Exhaust air passes through a series of filter banks including 36 Torit™ filters (filter efficiency of 99.99 % for particle diameters of one micron), 16 Mark 80 filters, and 16 high-efficiency particulate air (HEPA) filters (filter efficiency of 99.9995 % by laser spectrometer for particle diameters of 0.12 micron).

Process vessels are capped and conveyed through the RF oven over a time period of approximately 12 minutes. The RF operator monitors the processing time and temperature of the dielectric heater. According to Stericycle representatives, a homogenous temperature of 95°C is required throughout each vessel exiting the RF oven to ensure the deactivation of infectious organisms. The operator measures the temperature of the contents of the vessel by probing the vessel with a thermometer. If a temperature of 95°C is not achieved, the container is to be re-processed by placing the vessel back into the oven through the vessel re-entry door. At the time of the NIOSH site visit, exhaust air from the oven area was being recirculated into the containment room.

Stericycle has conducted efficacy testing recommended by the State and Territorial Association on Alternate Treatment Technologies, which reportedly defines a total required kill as the inactivation of vegetative bacteria, fungi, lipid/nonlipid viruses, parasites, and mycobacteria at a 6-$\log_{10}$ reduction or greater, and a 4-$\log_{10}$ reduction or greater of *B. stearothermophilus* or *B. subtilis* spores. The Illinois Institute of Technology Research performed the validation studies for Stericycle which were subsequently used to obtain an operating permit (issued by Washington State's Department of Ecology and the Lewis County Health Department).

After treatment, the heated containers of waste are stacked in a vessel storage area (see Figure 1) and held for a minimum of one hour. Following the heating and holding period, the contents of the containers are dumped by forklift into a baler or directly into a trailer. Each bale is 36" x 36" x 72" and weighs approximately 1,800 pounds (one bale is produced from the contents of three vessels). The composition of the deactivated waste is identical to that of the infectious waste except that it has been treated, shredded, rendered unrecognizable as medical waste, and reduced in volume by approximately 80 to 85 %. Bales are loaded onto a trailer (25 bales to a trailer) and transported to a landfill located in Arlington, Oregon.

At the time of the NIOSH site visit in January 1998, Stericycle had switched from operating three shifts per day (two production shifts and a maintenance shift) to operating one production shift per day. Two work crews, each consisting of 13 employees, alternate work days. According to management representatives, this change occurred in the middle of December 1997. It was not clear whether this revised work schedule resulted in a decrease in production rates. According to employees, approximately 2,300 pounds per hour (lbs/hr) are processed. The maximum production rate allowed by the Lewis County Health Department is 6,000 lbs/hr.

At the time of the initial NIOSH evaluation, employees working on the plant floor were wearing N95 respirators (as recommended by L&I), coveralls, hearing protection, impervious gloves and boots, and safety glasses. The wearing of N95 respirators was a new practice implemented in October 1997 as a result of the TB outbreak among Stericycle employees. In addition to the personal protective equipment (PPE) mentioned previously, in-feed station operators were also required to wear a safety line and face shields. Employees entering the containment area were required to wear Tyvek suits, impervious shoes and gloves, and airline respirators (with loose-fitting hoods). Laundry was cleaned on-site. Pre-employment physical examinations were required for all production workers. A tuberculin skin test (TST) was part of the pre-employment physical until late 1992, when a medical consultant suggested stopping this practice because medical waste workers were not considered at high risk for TB. In the NIOSH interim report (distributed on March 13, 1998), skin testing of employees at all ETD facilities was recommended.

Previous Investigations

Washington Department of Health (DOH) Investigation

From May through September 1997, three cases of active TB were reported to the Lewis County Health Department. All cases were current or recent former employees of the Morton Stericycle facility. Drug susceptibility testing for the three cases indicated that each case had a different susceptibility pattern, including one case of multidrug resistant TB. The different susceptibility patterns indicated that person-to-person transmission of TB among the three cases was not possible. A contact investigation was performed and failed to identify any person-to-person sources of infection for these three cases. Further laboratory testing confirmed that one of the cases had a strain of TB which was the same as that from a person treated at a facility that sends waste to Stericycle.[2] The three employees with active TB had worked at the following locations: tub wash station, in-feed station, and press room (refer to Figure 1).

Washington Department of Labor and Industries (L&I) Investigation

In response to an employee complaint alleging occupational exposure to Mtb and other biological agents, an L&I inspector performed a safety and health evaluation of the plant beginning on July 23, 1997. A walk-through inspection of the process was conducted, and all employees were interviewed as part of this inspection. The L&I inspector did not enter the containment room at the time of the site visit.

According to an L&I inspection report dated August 6, 1997, a safety flap had been missing from the chute opening at the in-feed station for at least two years. This flap was designed to prevent waste from being thrown back onto the plant floor in the event that the shredding equipment becomes clogged. Employees reported to L&I that the system would lose negative pressure when the shredders became clogged, and this resulted in air flowing from the processing containment room onto the plant floor. Employees referred to this as "blowback."

As a result of the L&I investigation, Stericycle, Inc. received a grouped-serious citation for exposing its employees to hazardous concentrations of biological agents which may arise from the processing, handling, or using of waste. Factors resulting in this citation included the following: failure to require employees to shower at the end of their shift, failure to require employees to thoroughly decontaminate their shoes in the change room after exiting the process area, and failure to require employees to wear their face-shields down at all times. Stericycle was also found to have failed to supervise and enforce their accident prevention program. Two general citations, corrected by Stericycle at the time of the inspection, were issued for failure to keep an Occupational Safety and Health Administration (OSHA) 200 log summary of occupational injuries and illnesses.

METHODS

Medical Evaluation

During the follow-up visit, NIOSH representatives offered to talk privately with interested employees; 6 out of 22 responded and were interviewed. We reviewed the OSHA 200 log and summary of occupational injuries and illnesses (form 200) for the years 1992-1997, available medical records for employees who reported occupational injuries or illnesses, and training materials from Stericycle. We also met with representatives from the Division of TB Elimination (DTBE)/Centers for Disease Control and Prevention (CDC), and with representatives from the Washington State DOH to discuss the Washington State DOH's epidemiologic investigation of three cases of active TB among Stericycle employees.

Environmental Evaluation

Airflow Visualization

Two different "smoke-like" aerosols were released to visualize airflow patterns. Inside the plant, a thin trail of "smoke" was generated by pushing air through a glass tube containing granules coated with a chemical substance that reacted with air. The smoke was released at several locations inside the plant, while the direction and velocity of the smoke was observed. For example, smoke was released to evaluate airflow in and out of the plant at doorways, to observe airflow patterns within the containment room, and to evaluate negative pressure at the face of the in-feed station opening.

A thick smoke from a theatrical fog generator was also released to determine if there were any visible leaks from the containment room and to detect possible routes for reentry of exhausted air back into the building. The smoke was first released inside the containment room to see if air from the containment room leaked into the plant. Later, smoke was released outside the building at the exit opening of the containment room exhaust located on the north side of the building. The path of the smoke showed the path of containment room air after it had been exhausted from the plant. Smoke was also released

into the opening of the in-feed chute to determine whether air at the face of the opening was captured by the ventilation.

Pressure Monitoring

The difference in pressure with respect to the main plant area was monitored at three locations: the in-feed chute, the containment room, and just inside the vessel re-load opening (see Figure 1). The in-feed chute was monitored with the pressure port located in three different positions. The first position was just inside the flaps along the top of the chute opening. Shortly before 3:00 p.m. on January 28, this port became dislodged during the installation of the tracer gas injection line, constituting a second "position" just outside the flaps along the top of the chute opening. At 6:00 a.m. on January 29, the pressure monitoring port was re-located to the vacated "deep," in-feed chute, tracer-gas injection line.

Tracer Gas Evaluation

Although chemical smoke is used to visualize air movement in the vicinity of a chosen location, a different type of marker is needed to quantify air distribution in a building or room. Tracer gases are useful for tracking the potential transport of agents that cannot themselves be monitored efficiently because their concentrations are too low, their release is sporadic, and/or detection methods are not available. Therefore, tracer gas was used in this evaluation to demonstrate the potential for spread of airborne infectious agents. Tracer gases must be quantifiable at concentrations which are known to be safe and not otherwise present in the environment. Sulfur hexafluoride is commonly used as a tracer gas. It is a colorless, odorless, nonflammable gas which is measurable at concentrations less than 1 parts per million (ppm). It has no known adverse health effects, and a permissible exposure limit of 1000 ppm has been established. Having few industrial applications other than the manufacture of electrical circuit devices, it is an ideal gas for detecting leaks and assessing the dispersion of pollutants.[3]

In this study, tracer gas was used to determine if there were any leaks or emission points from the process path or the containment room, and if there was any re-entrainment of exhausted air back into the building through either an open doorway or via the make-up air system. Seven sites were selected to monitor with MIRAN 203 infrared analyzers for the appearance of tracer gas: above the in-feed chute opening, on top of one of the safety storage cabinets between the entrance of the containment room and the office area, above the lid door opening, outside the right (west side) edge of the vessel re-load door opening, above the RF oven opening, at one of the supply openings for make-up air, and inside the open doorway on the north side of the building. B&K 1302 acoustic infrared analyzers were used to monitor tracer gas concentrations inside the containment room to determine if tracer gas leaked from the process line into the containment room itself and to monitor tracer gas concentrations passing through the building exhaust fans (see Figure 1).

Tracer gas was first released just inside the top edge of the in-feed chute opening, then deeper into the in-feed chute opening, inside the containment room, at the open overhead door on the north side of the building, and into the mixed make-up/return airstream. Except for monitoring inside the containment room with two MIRANs for less than an hour on January 27 and using one B&K as a roaming monitor, the sampling locations remained unchanged for the duration of the survey.

The tracer gas studies were conducted in 10 groupings of "injections" based on the location of tracer gas release. Five of these groupings involved the in-feed chute; two of these used the in-feed chute pressure monitoring port placed at the top of the chute opening behind the flaps; two used a separate tracer gas injection port at the top of the chute opening behind the flaps; and one group consisted of four releases from a tracer gas injection port positioned inside the in-feed chute opening, just below the bottom edge.

For the four releases of tracer gas which comprised the third grouping, the control valve of the NIOSH tracer gas cylinder was, unknown at the time to the investigators, leaking during the release of tracer gas.

This leak resulted in an additional, earlier source of tracer gas from the location of the compressed gas cylinder in the hallway between the containment room and the south wall of the building. After the leak in the control valve of the NIOSH tracer gas cylinder was discovered, the valve was removed from the injection line, and there were no leaks for any of the 14 subsequent injections. The injections with the leak were analyzed because they provide useful data. However, only the last two of these four releases have been used for analysis, since the first two releases were not fully captured by the dataloggers due to low battery power.

A sixth grouping consisted of two releases just inside the open overhead door on the north side of the building. One grouping consisted of two releases into the containment room, and two groupings involved the release of tracer gas into the containment room (one from just inside the flaps covering the vessel re-load opening and the other from just inside the opening used to load empty vessels into the processing room on the south wall of the containment room). The final grouping consisted of two releases at the intake of the make-up air fan.

Fluorescein Dye Solution

A dilute fluorescein dye solution, placed in 130 milliliter (mL) plastic specimen containers, was used to spike the contents of the Steritubs. The spiking of the Steritubs was accomplished by adding the sealed containers of dye to the Steritubs as the in-feed station operator removed the lid prior to dumping the contents into the in-feed chute. Steritubs were spiked throughout the day on January 27 and during the morning of January 28, 1998. As was the case with the tracer gas, the fluorescein dye was a surrogate contaminant which could be theoretically monitored efficiently at low concentrations. Fluorescein dye has been used previously in laboratory studies to demonstrate the generation of aerosols and leakage from equipment during routine procedures.[4]

To assess the presence of airborne fluorescein dye, 10 area air samples were collected on January 27, and 11 area samples were collected on January 28. Locations which were sampled on both days included the following: above the opening of the in-feed station, the tub wash station, the pit area in the containment room, the press room, the face of the vessel re-entry doors, and a control sample in the office. Locations sampled only on January 27 included: the change room, the exit of the RF oven, near the door leading to the cafeteria, and near the open bay door on the north side of the building next to the vessel storage area. Locations sampled only on January 28 included: on top of the control box located near the opening of the in-feed station, in the corner of a wall approximately four feet from the in-feed station, in a hallway approximately 12 feet from the in-feed station on the south wall, inside a truck being loaded with treated waste, and on top of the flammable storage cabinet located in the hallway by the entrance to the change room.

Samples were collected with Teflon® filters in closed-face, 37-mL cassettes. The cassettes were connected via Tygon™ tubing to Gilian Hi Flow Sampler™ battery-operated personal sampling pumps operating at a flow rate of two liters per minute (Lpm). Samples were collected during the time when bins were being spiked. Each filter sample was transferred into a 16 x 100 millimeter (mm) test tube and 5.0 mL of 0.01N aqueous NaOH was added. These tubes were rotated overnight and later sonicated for one hour. A portion of each tube was transferred to an autosampler vial for analysis. The samples were measured spectrofluorometrically at an excitation wavelength of 484 nanometers (nm) and an emission wavelength of 512 nm using a flow-injection technique. The sample was delivered to the detector flowcell with a mobile phase of 0.01 N aqueous NaOH at a flow rate of 1 mL per minute. Calibration curves were established and weighings of the standard Fluorescein were made. The neat standard was dissolved with 0.01N aqueous NaOH. Standards were prepared by serial dilutions of this stock solution with 0.01N aqueous NaOH. Spiked filters were prepared from stock solutions dissolved in methanol, water, and 0.01N aqueous NaOH in the range 0.05 to 0.25 micrograms (μg) and extracted and analyzed as above.

Bioaerosol Sampling

To determine the concentrations of culturable airborne bacteria, the Spiral Air Systems (SAS)™ Portable Air Sampler was used at a calibrated flow rate of 186 Lpm over a sample period of either one or two minutes, depending on the anticipated level of contamination. Two types of culture media were used: MacConkey agar was used for the collection of gram-negative bacilli, and Mannitol Salt agar was used for the collection of gram-positive bacilli. Speciation of bacteria was limited to three organisms: *Escherichia coli, Pseudomonas aeruginosa*, and *Staphylococcus aureus*. These bacteria were identified as being associated with medical waste streams (atypical environmental organisms), and were therefore utilized as indicators of whether or not aerosolization could occur. Total colony forming units (CFUs) for unidentified bacteria were reported by the laboratory as total Gram negative rods (GNR) if cultured on MacConkey agar and/or total bacteria if cultured on Mannitol Salt agar.

Duplicate air samples for culturable bacteria were collected over a three-day period (January 27-29) at the following seven locations: the press room, the pit of the containment room between the shredders, the change room, the in-feed station, the tub wash station, the loading dock, and the vessel re-entry doors. Control samples were collected in the office reception area and outdoors near the main entrance to the building. At each sample site, three replicate samples were collected with each type of agar.

Photos and Video

Photos of various equipment, work practices, and sampling methods and procedures were taken during the investigation. In addition, a video camera was set up at the in-feed station to document occurrences of "blowback," which Stericycle employees had previously reported to L&I and NIOSH investigators.

EVALUATION CRITERIA

Bloodborne Pathogens

Hepatitis B

One of the most infectious of all the known bloodborne pathogens is Hepatitis B Virus (HBV). Among health-care workers who have had needlestick injuries where the patient has had HBV infection, up to 30 % have developed infection with this virus.[5,6,7,8] Persons infected with HBV are at risk for chronic liver disease (i.e., chronic active hepatitis, cirrhosis, and primary hepatocellular carcinoma) and can potentially infect others. An estimated 100-200 health-care personnel have died annually during the past decade because of the chronic consequences of HBV infection (CDC, unpublished data). A vaccine for HBV is available, and the CDC recommends that workers potentially exposed to blood or blood-contaminated body fluids receive this vaccine.[9]

Hepatitis C

Hepatitis C virus (HCV) was identified in 1988 as the primary cause of non-A, non-B hepatitis, and as a major cause of acute and chronic hepatitis worldwide. HCV is most efficiently transmitted by large or repeated percutaneous exposures to blood, such as through the transfusion of blood or blood products from infectious donors and sharing of contaminated needles among injection drug users. The risk factors for HCV transmission in the occupational setting are not well-defined.[10,11,12,13] During the past decade, the annual number of newly acquired HCV infections has ranged from an estimated 28,000 to 180,000.[14] Of these, an estimated 2-4 % occurred among health care personnel who were occupationally exposed to blood.[15]

At least 85 % of persons with HCV infection become chronically infected, while chronic liver disease with persistently elevated liver enzymes develops in about 67 % of those chronically infected.[11] These extraordinarily high rates of chronic disease and persistent viremia in humans indicate the absence of

an effective neutralizing immune response.[16,17] Although postexposure prophylaxis after occupational exposure to HCV has been difficult to assess, immune globulin does not appear to be effective in preventing HCV infection.[18]

Even in the absence of available postexposure prophylaxis, individual worksites should establish policies and procedures for follow-up after percutaneous or mucosal exposure to anti-HCV positive blood to address individual worker's concerns about their risk and outcome. Employers should provide education to employees regarding the prevention of HCV in the occupational setting,[19] and such information should be routinely updated to ensure accuracy.

Human Immunodeficiency Virus (HIV)

The human immunodeficiency virus (HIV) is the cause of acquired immuno-deficiency syndrome (AIDS). Exposures to this virus can occur through needlesticks or cuts from other sharp instruments contaminated with an infected person's blood or through contact of the eye, nose, mouth, or skin with contaminated blood. All exposures of this type should be evaluated by a health-care provider.

Most occupational exposures to HIV do not result in infection. The risk of infection varies with the type of exposure and factors such as the amount of blood involved in the exposure, the amount of virus in the blood, and whether treatment was given after the exposure. Among health care workers, the average risk of HIV infection after a needlestick or cut exposure to HIV-infected blood from freshly contaminated sharps is 0.3 % (about one in 300).[20,21] Stated another way, 99.7 % of needlestick/cut exposures do not lead to infection. The risk of HIV infection after exposure of the eye, nose, or mouth to HIV-infected blood is estimated to be 0.1 % (1 in 1000), and the risk after exposure of the skin to HIV-infected blood is estimated to be less than 0.1 %.[22] There have been no documented cases of HIV transmission due to an exposure involving a small amount of blood on intact skin. The risk may be higher if the skin is damaged or if the contact involves a large area of skin or is prolonged. It is important to note that these data are for exposures that occur from contact with sharp objects or needles that are freshly contaminated. Since HIV (unlike HBV) does not survive long in the general environment, the risk of HIV infection from sharp objects that are not freshly contaminated, such as those present at the Stericycle plant, is probably lower than the risk among health care workers.

Treatment is available after an occupational exposure to HIV. Results from a small number of studies suggest that the use of zidovudine (ZDV) and other antiviral drugs after certain occupational exposures may reduce the chance of HIV infection after exposure.[21] However, a health care provider familiar with the risks of HIV infection and the side effects of the drugs should be consulted to determine whether post-exposure treatment is appropriate.

Tuberculosis (TB)

TB is an infectious disease caused by the bacterium Mtb. Mtb is carried in small airborne particles. These particles are so small (1-5 microns) that normal air currents keep them airborne and can spread them throughout a room or building. Infection occurs when a person inhales aerosolized Mtb and bacteria become established in the lungs and spread throughout the body.[23] Within 2 to 10 weeks after exposure, an infected person will usually have a positive tuberculin skin test (TST).

Most persons infected with Mtb will never have symptoms from this infection. The bacteria will be contained by the immune system and cause no overt illness, and the individual will not be contagious to others. In a small proportion of infected persons, the initial infection develops into "active" TB disease. With active TB disease, a person usually feels sick with cough, fevers, and weight loss and can infect others. To decrease the chance of developing active disease once infected, the CDC recommends that all persons with positive TSTs be evaluated for preventive drug therapy.[24]

Viability of Mycobacterium (Mtb) Tuberculosis

Although Mtb can take up to six weeks to grow in culture and requires fastidious conditions, once established, Mtb is quite hardy. Following the acute phase of rapid growth, older Mtb cultures may enter into a dormant state in which they demonstrate increased survival under adverse conditions, including temperature elevation and anaerobic conditions.[25,26] In fact, gradual depletion of the oxygen content of the cultures can produce reproducible stages of quiescence recognized by specific physiologic changes.[27]

Given gradual oxygen depletion, Mtb can survive in culture media containing 0.06 % oxygen in the dormant state.[26] Both young (0-3 days old) and old (15-35 days old) cultures were resistant to 90 minutes of heating in a 50°C (122°F) water bath. Heating to 53°C (127°F) for 120 minutes resulted in significant death in the younger cultures, but not the older cultures.[23] In an experiment to test the viability of Mtb in heat-fixed sputum smears, slides were prepared from patient sputum samples approximately 5 days old.[28] Using the standard flame technique, 99 % of the slides produced subsequent cultures. After hot plate heating for 120 minutes, 63 % of the slides heated to 65°C (149°F) yielded growth, as did 28 % of the slides heated to 85°C (185°F). Slides stained with phenol-auramine produced no growth. In another experiment, cockroaches were fed fresh heat-fixed sputum smears.[29] Fecal pellets were collected after four weeks and half of these were kept in a screw-capped glass jar in the dark for an additional 8 weeks. All were microscopically positive and produced positive cultures. Thus, not only did the bacilli survive the cockroach digestive process, but also the 8 weeks of dry storage in the fecal pellets.

In an older (1912), but very well documented study, the length of survival of Mtb under a variety of conditions was assessed.[30] This was of considerable interest at the time because the mode of TB transmission was still unknown. The methodology involved inoculation of guinea pigs with Mtb culture samples to confirm viability. Positive endpoints were the development of tuberculosis or a localized lesion that caused tuberculosis when inoculated into a second guinea pig. These were confirmed by culture.

In the initial experiment, it was found that Mtb exposed to sunlight for one minute survived, but Mtb exposed for two minutes was killed. Mtb culture suspension that was allowed to dry on sterile paper slips and subsequently cultured showed growth after four days, but not after eight days. In another phase of the study, an emulsion of cultured Mtb was made. Two hundred-fifty cubic centimeters of this emulsion were poured into a moistened, porous, 6-inch high flowerpot. The flowerpot was placed into a gallon sized glass jar which was filled with continually running water kept at a level of about three inches. After varying lengths of time, the flowerpot was scraped, the water spun, and the sediment made into guinea pig inoculum. After 307 days, viable Mtb was found, but not after 441 days. A guinea pig that died with disseminated TB infection was kept in running water in a similar manner. Tissue samples taken up to 321 days later contained viable bacilli. Sputum from a patient infected with Mtb was kept in the same fashion and contained viable Mtb for up to 187 days. In the final experiments, an emulsion of cultured Mtb was mixed into butter. Samples were kept at 20°C, 4°C, and -10°C. Viable Mtb were detected after 274 days of storage in each.

Guidelines for Controlling Occupational Transmission of TB

Criteria for evaluating the risk of TB transmission specifically in medical waste treatment facilities do not exist. However, the following basic approaches have been recommended to reduce the risk of TB transmission in health care settings: (1) prevent infectious particles from entering the air by providing rapid identification, isolation, and treatment of persons with active TB; (2) reduce the number of infectious particles entering the air by containing them at their source and by providing directional airflow and dilution ventilation; (3) use appropriate respiratory protection in areas where there is still a risk of exposure to Mtb; and (4) use

TST screening to identify persons with tuberculous infection, and provide preventive treatment (or treatment of active TB) when appropriate.

Screening and Early Identification of Persons Infected with TB

The identification of individuals with Mtb infection is commonly accomplished using the TST. The TST involves injecting a small amount of purified protein from Mtb into the upper layers of the skin. If the person being tested has previously been infected with Mtb, his or her immune system usually reacts against this protein. The reaction causes a reddish swelling at the site of the injection (a "positive" result if this swelling is of a certain size). If the person has not been infected previously, there will be little or no reaction (a "negative" result). There are standardized guidelines for interpreting the TST results.[23,31] The injection does not contain live Mtb bacteria and cannot cause Mtb infection; furthermore, repeated skin testing will not cause a positive test in a person who has not been infected with TB.

If a person with a previously negative skin test reacts positively to a TST, the test should be followed by a chest x-ray to determine whether active TB has developed. Prophylactic (preventive) drug therapy is generally prescribed upon diagnosis to prevent the infection from advancing to active TB disease.[23] Some strains of Mtb are resistant to the most commonly used drugs, necessitating the use of other pharmaceuticals.[32] In addition to identifying individuals for whom treatment is appropriate, routine TST screening can also serve as a surveillance tool to identify areas or occupations for which there may be an increased risk of TB transmission.

It should be noted that even if the drug treatment successfully kills the Mtb and prevents the development of active disease, the patient will continue to test positive on later TB skin testing because his or her immune system will "remember" the TB protein and react to the skin test.

RESULTS

Medical Evaluation

Interviewed employees reported that some needlestick and other sharp object injuries, as well as splashes to eyes, nose, mouth, or skin were not always reported to the company. It was clear from the interviews that some employees did not understand the seriousness of the health risks from these exposures and the need for prompt follow-up. Interviewed employees reported uncertainty about the order in which to put on and remove PPE, and reported that they have been discouraged from using PPE during spill responses in the production area.

A total of 31 medical records were reviewed of both current and former employees. Medical records revealed that employees were not receiving two-step tuberculin skin testing at their initial tuberculosis screening. In addition, not all employees received all three doses of the Hepatitis B vaccine, and few employees were tested for antibody to hepatitis B surface antigen after receiving the 3-dose series or after incurring a needlestick or other sharp object injury.

Review of OSHA 200 logs from 1992 through 1997 showed differences in the needlesticks listed on the logs, and the medical records of needlestick injuries that were found during the medical record review. NIOSH did not review medical records for all employees, but for those records that were reviewed, NIOSH found five OSHA 200 log reports of needlesticks, three of which were not mentioned in the medical records. NIOSH also found five reports of needlesticks in the medical records that were not listed in the OSHA 200 logs.

Environmental Evaluation

Findings and Observations

NIOSH investigators observed the following regarding the use of respiratory protection, work practices related to the containment room, the

potential occurrence of "blowback," employee training, and work practices:

Respiratory Protection

During the initial site visit (November 18-20, 1997), NIOSH investigators detected odors in the containment area while using the company-supplied airline respirators with loose-fitting hoods. Several employees reported that odors could be detected at times while wearing the respirators. According to safety meeting minutes supplied to NIOSH by employees, problems had been identified with the airline respirator system as early as May 3, 1995. Notes compiled from several meetings pointed out the following deficiencies: the system was not able to accommodate more than one user, repeated requests for a back-up respirator had not been satisfied, one of the hoses for the airline respirator was in need of repair, and there was concern among employees that the supply air compressor was not providing enough pressure (the employees questioned whether the air filter was clogged). An internal memo written by management representatives, dated May 15, 1996, stated that two of the three air-line hoses for the press room did not stay attached to the air-line hood/respirator and the air-line reels were not staying unrolled unless someone held the hose. Therefore, it was concluded by the management representative that only one person could "safely" work in this area at a time.

During the follow-up visit in January, NIOSH investigators were informed by management that the airline respirator system had been evaluated and several changes had been made, including the replacement of the particulate filters, relocation of the air connection points, increasing the flow rate of air supplied to the hoods, and replacement of the supply air hose (using a larger diameter to increase flow). Upon further evaluation and discussion with a representative of the respirator manufacturer during this site visit, it was determined that the system, as it existed, did not meet with NIOSH approval. Since some of the replacement parts were not selected from those listed on the NIOSH approval list (TC-19C-154), they had not been adequately evaluated as part of the system. In addition, to achieve the higher airflow rate observed during the January visit, the supply air compressor was operating near its peak back pressure, which is not recommended by the pump manufacturer.

Disposable N95 respirators were being worn on the plant floor by all employees at the time of the initial NIOSH site visit. In mid-December, Stericycle decided that respirators were no longer needed on the plant floor, since no new positive TB skin tests had been found among current employees. However, a letter issued to Stericycle by L&I on December 22, 1997, stated that the "use of appropriate respirators within the plant is a necessary measure to protect against future exposure, at least until the specific methods of transmission can be identified and appropriate engineering controls implemented." At the time of the NIOSH follow-up visit during the last week of January, respirators were being worn by only a few workers (e.g., in-feed station operators and tub washers).

Many employees reported to NIOSH investigators that respirators were difficult to wear due to the accumulation of sweat and/or condensation inside the respirator. It was also reported that the tub washers' respirators become wet due to the steam from that process (the worker's face is located above the steam bath). Although fans had been mounted above the workers, they were not effective in removing steam from the area surrounding the employees.

Containment Room

The company's bloodborne pathogen policy stated that all doors to the processing room and press room were to remain closed. To enter the containment room, employees had to enter through a "change room," where protective clothing was stored. This room was inappropriately being used as both a "clean" change room (storing of protective clothing) and a "dirty" change room where contaminated clothing was removed and discarded. Eye wash stations and hand wash stations were not available inside this area. On several occasions during the NIOSH site visit, both doors in the change room (one leading from the plant floor into the room and one leading from the room into containment) were open

at the same time. In addition, the door to the change room from the plant floor was left open on several occasions (the doors are not self-closing).

Other openings (not employee entrances) to the containment room included the in-feed station, a garage door by the in-feed station, the vessel re-load entrance, the vessel lid opening on the east wall of the press room (allows lids to be fed into the containment room), and the opening for the vessel conveyor system located on the south wall of the containment room. Employees reported that, in the past, the garage door to the containment room had been left open at the end of the shift prior to fogging the room for decontamination.

Soiled, disposable Tyvek suits were being re-used by employees during the January site visit. After exiting the containment room, employees would either hang up their Tyvek suits and hoods, or place them in a locker in the change room. The company's policy manual stated that Tyvek suits should be discarded in biohazard bags in the change room; however, waste bags were not present until the last day of our site visit. Upon re-entering the change room, employees would "shake out" the used Tyvek suits thus potentially aerosolizing infectious agents. Gloves were not worn while handling the soiled Tyvek suits. In addition, the interior necklines of most of the supplied-air hoods hanging in the change room were heavily soiled. This issue was addressed in the recommendations section of the interim report (March 13, 1998).

Due to the design of the respirator system, employees had to enter the containment room before connecting the supplied air hose to their respirators. This practice could have potentially exposed the wearer to infectious aerosols.

Occurrence of "Blowback"

According to employee safety meeting minutes supplied to NIOSH by employees, the occurrence of "blowback" was documented at the Morton facility as early as June 16, 1995. During this meeting, employees reported that when the system was clogged, air would visibly push the curtains out towards the plant floor. Management representatives indicated that a new system was going to be installed to prevent this from occurring.

During the second NIOSH site visit, a video camera was placed at the in-feed station to document potential occurrences of "blowback." Employees reported that this occurs when either the primary or secondary shredders become clogged. On the first day of sampling, we witnessed one such occasion when the primary shredder became clogged. The flaps at the in-feed station were observed to intermittently blow outward. Use of a smoke tube confirmed that air inside the in-feed chute was blowing back towards the in-feed station operator. The cause of the positive pressure air movement was undetermined. Stericycle management representatives were made aware of our observations at the time this occurred as well as during the closing meeting.

Training

While written training policies met the appropriate regulatory requirements, many employees did not appear to understand general infection control principles, the potential hazards associated with the infectious waste processed at the facility, as well as task-specific safety procedures. For example, employees were observed removing their personal protective clothing in the change room after exiting the containment room. In most instances, the order in which the contaminated clothing was removed could potentially contribute to cross-contamination of the employees' hands, storage lockers, and other equipment. Although employees reported that they received training on the appropriate clothing to wear while in containment, they reported that they had not received training on how to remove and discard the contaminated materials. Employees also expressed concern regarding appropriate spill response training. In addition, there was confusion among employees regarding the appropriate personal protective equipment to be worn in the event of an accident or spill.

According to employees, and confirmed by our observations, employees have been placed in

situations where they have been required to perform jobs for which they have not received adequate training. For example, during the initial site visit, an employee was required to switch from the tub wash area to the in-feed station without receiving job-specific training.

Inconsistencies were identified during discussions with management representatives regarding training requirements among Stericycle facilities. For example, "safety tests," which are required at other Stericycle facilities as part of employee training, reportedly had not been administered to employees at the Morton facility.

Work Practices

Stericycle policy requires a homogenous temperature of 95°C in each vessel after exiting the RF oven to ensure the inactivation of infectious organisms. However, NIOSH investigators observed temperature probing techniques that would not accurately measure homogeneous temperatures of the treated material. According to interviews conducted with employees during both site visits, vessel contents not reaching 95°C were occasionally disposed of without being re-processed appropriately.

After prolonged use, carbon accumulates on the surfaces of the cooking vessels causing the vessels to "arc" while being processed in the RF oven. The carbon is removed from the vessels by grinding the interior surfaces. During the initial site visit, we observed a vessel which had caught fire while being removed by a fork-lift. An employee was observed spraying it down with water. There was no written operating procedure addressing the frequency with which vessels should be cleaned to avoid a fire hazard.

According to the company's operating plan, in the event the process is shut down, all waste is to be sent to a Stericycle incinerator facility in Oregon. The operating plan, however, did not specifically state how this will be accomplished. According to employees, on one such occasion, they were instructed by management representatives to remove infectious waste from the Steritubs and place it into cardboard boxes for incineration. According to Stericycle management, this occurred in March 1997.

Exhaust air from the RF oven was originally exhausted outdoors; however, due to odor complaints from the community, Stericycle changed the process to recirculate the exhaust from the oven into the containment room. This change reportedly occurred approximately two years prior to our investigation. According to employees, it appeared that filters in the containment room became clogged more often as a result of the heated air being exhausted into the humid environment in the containment room. At about that same time, a change in the style of Torit™ filters was made by the manufacturer. According to employees, clogs appeared to occur more frequently with the new filters (beginning approximately two weeks after installation) than the older style filters.

It appeared that the incentive pay system may have contributed to employees overlooking or bypassing safety-related practices and procedures. Incentive pay is based on the number of tubs processed in excess of 1,260 per shift. For instance, employees reported that Torit™ air filters were removed from the filter bed of the process exhaust ventilation when they became clogged or wet because it would slow the process down. Instead of maintaining a readily available stock of new filters at the facility, management representatives would reportedly instruct employees to remove several of the filters from the filter bed. Another method reportedly employed to process waste at a faster pace involved removing "un-cooked" vessels containing infectious waste from the containment room through the vessel re-load doors. Management representatives stated that they were unaware of this practice.

Used Torit™ filters are reportedly stored in the pit of the containment room and cleaned with compressed air; however, the manufacturer's specifications state that the filters should be cleaned by "pulse cleaning" or with water. The specifications also state that a lower filtration efficiency may result from cleaning them with water (they must be dried thoroughly

before reinstallation). Employees reported that the air HEPA filters have also been cleaned with compressed air. The use of compressed air to clean both types of filters is not advised since it may damage the filter bed, and for HEPA filters, would invalidate their certification unless further testing was conducted. In addition, the use of compressed air may re-aerosolize contaminants into the environment.

According to management representatives, the HEPA filters used in the containment room were leak tested with smoke when they were first installed in 1992. Although the filters are reportedly changed every 6 to 12 months, they had reportedly not been leak tested since their installation.

Airflow Visualization

Smoke from the smoke tubes showed that air entered the plant through the overhead door on the north side of the building, as well as through the overhead doors on the loading dock. From the northwest corner and west end of the inside of the building, the air flowed towards and around the containment room in a generally south and east direction. Once around the containment room, air in the plant flowed generally north and east to the two exhaust fans high on the east and north walls at the east end of the building.

Some air also entered the plant through the make-up air opening in the north wall of the building, although the "make-up air" fan was also supplied with air recirculated from inside the plant. This air was blown into the plant in two streams, one in a southwest direction, the other in a southeast direction. These two flows soon merged with the general flow previously described.

Smoke released inside the containment room swirled around with a relatively high velocity. The smoke was dispersed quickly, and eventually exhausted through the inlet to the filter auger fan and through openings on the inlet side of the primary and secondary mill negative air fans. No visible smoke was observed escaping the containment room or the processing room; and, within that suite of rooms, air flowed from the press room into the pit of the containment room.

Smoke released outside near the containment room exhaust on the north wall of the building (on January 28) was blown down to and in through the open overhead door on the northwest side of the building. Winds were out of the east/southeast at the time.

Smoke released behind the upper left-hand side of the plastic flaps located inside the in-feed chute was mostly drawn into this chute. However, some smoke was caught in the wake formed around the opening of the waste container that was being pulled back from the in-feed chute after the contents had been dumped into the chute. A portion of this smoke escaped from the chute to the plant floor.

Pressure Monitoring

The pressure measured inside the containment room and just inside the vessel reload opening remained negative with respect to the main area of the plant. Six times during the periods that pressure was monitored on January 28 and 29, the negative pressure doubled in comparison to the levels maintained over the other 95 % of the time. These significant pressure shifts, which lasted from one to five minutes, occurred at approximately 11:40 a.m., 1:25 p.m., 2:25 p.m., and 4:15 p.m. on January 28 and 7:05 a.m. and 9:45 a.m. on January 29. These pressure changes were most likely related to clogging of the process line.

The pressure measured in the in-feed chute at the location along the top edge of the opening, just inside the flaps, was mostly negative. About 20 % of the time on January 28 before 2:56 p.m., the pressure fluctuated between positive and negative values of approximately the same magnitude. When the containment room pressure became twice as negative during this period, the pressure measured inside the flaps along the top edge of the in-feed chute became positive. This indicates that during a clog, air from inside the flaps might have been discharged out of the in-feed chute.

After the pressure monitoring port became dislodged at 2:56 p.m., the pressure measured just outside the opening of the in-feed chute became mostly positive, with some negative values about 20 % of the time. The one time the containment room pressure became twice as negative after the pressure monitoring port became dislodged, the pressure measured just outside the opening to the in-feed chute became more positive. The significance of these pressure values from the dislodged monitoring port is less clear. However, occurrence of the more positive readings at the same time the pressure in the containment room became more negative, supports the conclusion that a process line clog was responsible.

The pressure measured on January 29, at the "deep" location below the bottom edge of the in-feed chute opening, was always negative. The two times that the pressure in the containment room became about twice as negative as the level maintained the other 95 % of the time, the pressure below the bottom edge of the in-feed chute became less negative, but did not become positive. This indicates that during a clog, air from deep inside the in-feed chute may not be discharged out of the in-feed chute. However, particles propelled by the action of the primary shredder would probably have been able to overcome the small negative pressure and could have been ejected from the in-feed chute.

Tracer Gas Studies

The first day's (January 27) releases were range-finding tests to determine if the quantity of tracer gas which needed to be released to be detected at the various monitoring locations was adequate. The initial amount of tracer gas released that day was, in fact, too small to be detected inside the plant. However, it was sufficient to show that tracer gas released into the process line could be detected in the containment room.

On January 28 and 29, tracer gas was detected inside the plant when a much larger quantity was released for each injection. The existence of a leak from the control valve of the NIOSH tracer gas cylinder for the injections on January 28 up until 11:30 a.m., though unintended, demonstrated the unique profile of tracer gas concentration from a source near, but not inside, the in-feed chute. The characteristics of this profile resulted in large, sharp peaks which appeared quickly at the monitoring locations on top of one of the yellow safety storage cabinets, above the oven outlet opening, and just above the lid-door opening. This became a model with which to compare the monitoring responses for the releases of tracer gas inside the opening of the in-feed chute, to assess the presence of any discharge back out of the in-feed chute.

After the leaky control valve of the tracer gas cylinder was removed, much smaller and more rounded peaks of tracer gas were detected at the safety storage cabinet, lid-door, or oven opening. These peaks appeared only after being detected at the (open) overhead door on the north side of the building. Although this negative result is not conclusive, the absence of large, sharp peaks indicates that not much, if any, discharge from the opening of the in-feed chute occurred when there was no leak. Large, sharp peaks were again detected when tracer gas was released just inside the overhead door; however, the delayed appearance times and relatively smaller peak heights at the safety cabinet, oven opening, and lid door opening were more like the injections without a leak.

The values of appearance times, relative peak heights, and the peak rise times for six monitoring locations are presented in Tables 1, 2, and 3, respectively. These results cover seven injections into the in-feed chute and two releases just inside the open overhead door. Individual high or low values, without corroborating data from the same release condition to indicate a trend, will not be discussed.

For ease of interpretation, the appearance times in Table 1 are presented as the number of seconds before (negative numbers) or after (positive numbers) the time that tracer gas appeared at the vessel reload opening, monitoring location. This location was chosen because smoke-tube airflow visualization had shown that it was not in the path of air movement from the opening of the in-feed chute to the exhaust fans in the northeast corner of the building. If tracer gas was detected at the other

monitoring locations in this general area before being detected at the reload opening, it would indicate a leak from the in-feed chute.

The times for the safety cabinet, oven opening, and lid door opening were drastically different when there was no leak in the cylinder valve, indicating those locations were in the path of the air movement from the cylinder valve, and that there was no leak from the in-feed chute during normal (no clog) operation. The times for the make-up air location and overhead door indicate these two locations were not in the path of the air movement from the leak in the cylinder valve. The longer, relatively more consistent times for the overhead door for the releases from the overhead door indicate that tracer gas reached this location after being recirculated.

The rise times in Table 2 are the actual number of seconds required for the tracer gas concentration to reach a peak from the time that tracer gas appeared at each monitoring location. The shorter rise times for the safety cabinet, oven opening, and lid door opening when there was no leak in the cylinder valve, again indicate they were close to the point of the leak from the cylinder valve, while the make-up air location and overhead door were not. The longer rise times when there was no leak in the cylinder valve, again indicate tracer gas was not discharged from the in-feed chute during normal (no clog) operation.

Since the quantity of tracer gas released would not be expected to be the same for each injection, the peak heights in Table 3 are presented as the ratio of the peak height at the monitoring location relative to the peak height at the reload opening monitoring location. The larger peak-height ratios for the safety cabinet, oven opening, and lid door opening when there was no leak, again indicate they were close to the point of the leak. The much smaller ratios at the overhead door for the releases from the overhead door support the suggestion that tracer gas reached this location after being recirculated.

Fluorescein Dye

Due to poor precision and accuracy data from the analytical quality assurance spikes, quantifying dye concentrations collected on the filters was not possible. Therefore, only qualitative results are reported; a positive signal indicated that fluorescein dye was present on the filter. On January 27, positive signals were observed for samples collected in both the pit of the containment room and the press room. On January 28, positive signals were observed from samples collected in the pit of the containment room, the press room, and two samples collected at the in-feed station. The cause of the problems associated with the spiked samples was not determined, but the "wettability" of the Teflon® filters by the 0.01N aqueous NaOH was a potential factor.

Bioaerosol Samples

The results of sampling for culturable airborne bacteria are presented in Table 4. The reported concentrations are averages of three replicate samples collected each day at each site on both types of agar. For example, concentrations reported for samples collected in the press room on January 27 are averages of sample numbers 4, 5, and 6. Sample locations are listed in the table in decreasing order according to overall concentrations.

Bioaerosol evaluation criteria do not exist for the assessment of what would be considered "safe" for workers processing medical waste. However, sampling results can be useful by comparing the concentrations and predominant species of organisms found in suspect exposures sites with samples collected at control locations. For example, at Stericycle, the sample locations (potential emission points) chosen included (1) the press room, (2) the pit of the containment room between the shredders, (3) the change room, (4) the in-feed station, (5) the tub wash station, (6) the loading dock, and (7) the vessel re-entry doors. It was anticipated that the concentrations of organisms associated with medical waste would be the highest inside the processing area (press room and containment room). As previously described in the Background section of this report, the shredding and compacting process is carried out in an enclosed area which is operated

under negative pressure. Control sample locations included (1) the office reception area and (2) outside near the main entrance to the building.

Bioaerosol concentrations in the press room were the highest. Total concentrations of both GNRs and Gram positive bacilli (including the three speciated organisms) ranged from 140 colony forming units per cubic meter (CFU/m^3) on January 28 to a concentration of 523 CFU/m^3 on January 29. The process was not operating during the collection of the samples on January 27. All three organisms considered to be associated with medical waste (*Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus*) were cultured from the air in the press room.

Comparable bioaerosol concentrations were found from samples collected at the in-feed station, the pit of the containment room, and the tub wash station. The highest concentration of total airborne bacteria (including both Gram negative and Gram positive bacilli) among these three areas (217 CFU/m^3 at the in-feed station on January 29), was approximately half the highest concentration found in the press room. However, total airborne bacteria concentrations were slightly higher at the in-feed station (outside the containment area) than the pit area inside the containment room (due to the small sample size, this difference was not statistical significant). As was found in the press room, sample concentrations were significantly higher on January 29 at all three locations. *Pseudomonas aeruginosa*, *Escherichia coli*, and *Staphylococcus aureus* were all cultured from the air in the pit of the containment room over the 3-day sampling period; these organisms were not identified in the samples collected from the in-feed and tub wash stations. *E. coli* was cultured from two areas: the press room and the pit.

Concentrations of total bacteria were consistently higher on January 29 at 7 of the 9 locations compared to the previous two days of sampling. The two locations where concentrations appeared to be similar on all three days were the change room and the outdoor control sample. Samples collected outdoors revealed the lowest concentrations (3 CFU/m^3 was detected on January 27, while no growth was observed on January 28 and 29).

None of the three organisms associated with the medical waste were identified in samples collected at the control locations. *Pseudomonas aeruginosa* was cultured from three areas: the press room, the pit, and the change room. *Staphylococcus aureus* was cultured from three areas: the press room, the pit, and the loading dock (the particular sample on the loading dock was collected during the unloading of bins on January 27). GNRs were detected on all samples except those collected in the control locations (reception area and the outdoor air). Gram positive organisms were detected on all samples.

DISCUSSION

Smoke patterns indicated that small quantities of air may overcome the capture velocity at the face of the in-feed chute. Although the ventilation at the in-feed chute seemed adequate most of the time, there are three situations that may result in ventilation problems: (1) dumping waste from the Steritubs into the in-feed chute, (2) clogging of the process line, and (3) re-entrainment of exhaust air from the containment room.

Dumping of the Waste

During dumping of the waste from the Steritubs into the in-feed chute while the shredder and mill were processing the waste, there was a reduction in total airflow through the in-feed chute. Coincident with this reduction in airflow was a disruption of flow due to the presence of the Steritub waste container in the mouth of the in-feed chute. A wake formed behind this container could have caused a negative pressure zone which could pull air from the in-feed chute back out into the plant as the container was removed by the operator.

Clogging of the Process Line

When there is a clog, the flow of air through the in-feed chute may be drastically reduced and may even

stop. During these times, bacteria and other organisms or toxins present in the waste may be aerosolized and can escape out of containment into the plant. This particular situation occurred on the first day of sampling when the primary shredder became clogged. The flaps at the in-feed station were observed to intermittently blow outward and a smoke tube evaluation confirmed that air inside the in-feed chute was blowing back towards the in-feed station operator. According to employees, "blowback" has been a documented problem at the Morton facility for at least three years. Under these circumstances, aerosolized waste could remain suspended in the plant air for an hour or more until completely removed by the general ventilation. Theoretically, over 99 % of a contaminant might be removed from a room in an hour if the air is well-mixed and the air change rate is 7 air changes per hour. However, in most rooms, there may be localized areas which are poorly ventilated or portions of the room where the air is poorly mixed. Consequently, some of the contaminant could possibly remain in the room for several hours.

Re-entrainment of Exhaust Air

The building was under negative pressure with respect to the outside, so air entered through any open doorway as well as through cracks around doors, including the overhead doors on the loading dock, and anywhere that building panels do not fit tightly. The primary routes for air from the process line to get into the main part of the plant were through the overhead door on the north side of the building and through the make-up air system, depending on the prevailing winds. When the wind is from the east, exhausted air could enter through the overhead door. When the wind is from the west, exhausted air could enter through the make-up air system. The re-introduction of exhausted air should not be a problem as long as there is no leakage through or around the HEPA and Torit filters. Leak testing had not been performed by Stericycle since the operation began in January 1992.

Tracer gas results collected at the time of the evaluation appear to indicate that air in the containment room does not escape into the main plant area under normal conditions (except for the conditions mentioned above).

The air in the containment room was drawn into the processing exhaust stream; likewise, the tracer gas results indicated that air from the process line escaped into the containment room. In the containment room, air was found to mix well.

When tracer gas was released inside the overhead door (refer to Table 1), it appeared back at the overhead door in approximately two minutes. This indicates that some of the air exhausted from the building through the processing stream exhaust will reappear in the plant within two minutes. The reappearance and time required could vary depending on the direction and speed of the prevailing winds.

Air was exhausted from the plant by the two wall fans on the north and east walls and by the process line. The two wall fans were rated at a total of 30,000 cubic feet per minute (CFM), and the primary and secondary mill negative air fans were rated at 7,000 CFM each. Since the primary and secondary mill fans are in series, their air moving capacity would not be additive, so the total rated exhaust rate for the plant would be around 37,000 CFM. The air change rate calculated from decreasing tracer gas concentrations was somewhat less at 30,000 CFM. This indicates that the loads on these fans may be somewhat higher than expected by the designers.

CDC recommends that laboratory waste be decontaminated prior to leaving the facility for disposal. A study, further supporting this recommendation, resulted in the conclusion that compaction of infectious waste can result in significant releases of bioaerosols into the environment.[33] This study stated that treatments commonly used for infectious waste (such as compaction or shredding) have been strongly discouraged or prohibited by others due to the risk of aerosolizing infectious agents. Bioaerosol samples collected at the Morton facility indicated the potential for aerosolization of infectious organisms inside the containment room as well as on the plant

floor. While concentrations of bacteria cultured from the press room were much higher than at all other sample locations, samples collected in the pit of the containment room, the in-feed station, and the tub wash station were similar. This finding was of particular concern since concentrations on the plant floor (in-feed and tub wash stations) were expected to be significantly lower than those found inside containment. From the concentrations alone, it could not be determined whether samples collected on the plant floor were similar to those found in the pit due to (1) the escape of contaminants from the containment area or (2) the presence of airborne organisms from the opening and washing of Steritubs. The latter condition appears to be more likely, since the three speciated organisms were only present on the samples collected inside the containment area.

Regardless of the type and originating point of the airborne organisms, the concentrations collected on the plant floor from these two locations were approximately two times greater than those collected from the control sampling areas. Further evaluation needs to be conducted to determine the cause of the elevated concentrations found on January 29 in comparison to the previous two days of sampling. Potential reasons for this increase may be higher production rates or the types of waste processed on that specific day.

In addition to the bioaerosol samples, the airborne flourescein dye samples further indicate that the potential for aerosolizing medical waste components exist at the Morton facility. Dye was present on all filter samples collected inside the containment area and on two filter samples collected at the in-feed station on January 28.

According to the manufacturer of the oven, the heat achieved by the RF unit is determined by several factors including the specific heat of the materials in the vessel (different materials will absorb temperature at different rates), the weight of the materials in the vessel, and the moisture content. Due to the variation of the materials in the waste, heat may not be uniformly absorbed by the materials due to the varying specific heat of the contents. Although Stericycle stated that the press operator was responsible for creating a 10 to 15 % moisture content within the vessels, this activity was not monitored. Moisture content is also affected by the presence of blood and body fluids. In addition, the RF operator did not measure temperature in a predetermined number of locations to assess even heating.

CONCLUSIONS

While the DOH investigation determined that infection with Mtb in at least one of the Morton facility employees was likely a result of exposure to contaminated waste, the NIOSH investigation could not confirm the particular source of the exposure. Many of the original conditions and practices that may have contributed to the outbreak of TB had been changed prior to the request for the NIOSH investigation. An attempt to document these conditions was made by interviewing employees and reviewing available records.

NIOSH identified several factors present in the Morton facility that could result in employee exposures to aerosolized bacteria (including Mtb) and bloodborne pathogens. Some of the major factors included the following:

- the use of a process that creates the potential for aerosolization of the products contained in the waste prior to deactivation due to the shredding and compacting of the infectious waste;
- deficiencies in the design of the ETD process which results in the frequent clogging of the process line, and a ventilation system which is unable to ensure that the in-feed chute will remain under negative pressure when such clogs occur. When clogs occur, employees must come in direct contact with the waste (including exposures to needles and other sharps);
- the use of inadequate airline respirators in the containment room;
- inadequate implementation of policies at the facility to ensure that employees report and receive follow-up care when a potential exposure occurs;

- the lack of a preventive maintenance program to ensure that the equipment and operation of the equipment used at the facility is working properly including leak testing of the HEPA filters used in the processing line;
- misconceptions among employees about operations, PPE, and policies and procedures based on implementing an inadequate training program which was not site specific to the work practices performed by workers at Stericycle.

Based on the fact that (1) Mtb is known to be a very hardy organism which can survive for long periods of time under a variety of adverse conditions, (2) that the Morton facility processes infectious waste (including cultures of Mtb) which is not deactivated until the waste has been shredded and compacted, and (3) that Stericycle uses a process that creates the potential for aerosolization of the products contained in the waste (including Mtb), NIOSH concludes that employees could be exposed to pathogens potentially present in the medical waste.

RECOMMENDATIONS

The following recommendations should be implemented at the Morton facility and may be applicable at all of the Stericycle facilities where the ETD process is used.

Bloodborne Pathogens

Immediately following an exposure to blood or body fluids, or to objects potentially contaminated with blood or body fluids, the following should occur: areas of skin exposed to needlesticks and cuts should be washed with soap and water; after splashes to the nose, mouth, or skin, the area should be flushed with water; and after splashes to the eyes, the eyes should be irrigated with clean water, saline, or sterile irrigants.

All employee needlesticks, cuts from other sharp objects, or splashes onto the skin, eyes, nose, or mouth should be immediately reported and evaluated by an appropriate health care professional. Stericycle should have a program in place that emphasizes and ensures that this reporting and medical follow-up is taking place.

In accordance with CDC recommendations for health care workers, all Stericycle employees should be vaccinated with the HBV.[8] One to two months after completion of the 3-dose vaccination series, employees should be tested for antibody to hepatitis B surface antigen (anti-HBs). Persons who do not respond to the primary vaccine series should complete a second 3-dose vaccine series or be evaluated to determine if they are hepatitis B surface antigen (HBsAg)-positive. Re-vaccinated persons should be retested at the completion of the second vaccine series. Nonresponders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain hepatitis B immune globulin (HBIG) prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood. Booster doses of hepatitis B vaccine are not considered necessary, and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended.

Employees should be provided with accurate and up-to-date information on the risk and prevention of infection from all bloodborne pathogens. After any sharp injury or splash to the eyes, nose, or mouth, workers should discuss with their health care provider the need for post-exposure treatment and follow-up. [19, 36]

Tuberculosis (TB)

Medical waste treatment facility employees do not currently fall into the CDC's defined high-risk categories of workers thought to be at an elevated risk for Mtb infection. However, the DOH investigation indicates occupational TB transmission at the Morton Stericycle facility, and because workers are potentially exposed to medical waste that may be contaminated with Mtb, we recommend that employees continue to be monitored for Mtb infection.

The TB screening programs should follow the 1994 CDC Guidelines[22] and should be developed in consultation with qualified medical and/or public health personnel at the state or county health departments. Employee representatives should be involved in the development of the policy and program. The program should be offered at no cost to employees.

Individual TST results and clinical evaluations should be maintained in confidential employee health records, and should be recorded in a retrievable aggregate data base of all employee test results. Identifying information should be handled confidentially. Summary data (e.g., the percentage of positive reactions among all tested) can be reported to management and employees. Other than reporting to the tested individual, and to public health authorities in the case of TB, results should remain confidential.

The rate of skin test conversions should be calculated periodically to estimate the risk of acquiring new infection and evaluate the effectiveness of control measures. On the basis of this analysis, the frequency of re-testing may be altered accordingly.

TB education of employees should be continued. This education should be performed in consultation with qualified medical and/or public health personnel. The training should cover the basic concepts of TB transmission, pathogenesis, diagnosis, signs and symptoms, proper precautions for minimizing risk of infection and active disease, purpose of testing, interpretation of TST results, principles of drug therapy, and follow-up procedures for TST conversions and suspicion of active disease. Additionally, periodic updates should be provided to disseminate new information about TB and to share summary information about the extent of Mtb infection among employees.

Personal Protective Equipment (PPE)

As recommended by L&I, all employees should continue to wear appropriate respiratory protection while working on the plant floor. Results of bioaerosol and fluorescein dye sampling further indicate the need for continued use of respiratory protection. Respirators will not be required on the plant floor under two conditions: (1) after the plant has gone through the general housekeeping and general area plant fogging procedures for decontamination after a sufficient amount of time has passed to remove 99 % of particles from the room air, and (2) when the plant is not operating. After the pit has been fogged, employees are required to wear a full-facepiece HEPA-filtered negative pressure respirator at a minimum while in the pit. Methods to minimize the accumulation of condensation inside the respirators or more frequent respirator changes should be encouraged among employees, since this may compromise the worker protection fit factor.[34] Stericycle employees should also be reminded that facial hair is prohibited with the use of negative-pressure respirators because it interferes with the proper seal of the respirator to the face.

During the closing meeting, NIOSH stated that the airline respirator system used inside the containment room should be immediately upgraded to meet NIOSH approval, and that alternative appropriate respiratory protection should be worn in the interim. Replacement parts must be selected from those listed on the NIOSH approval list (TC-19C-154), to ensure that they have been adequately evaluated as part of the entire system. In addition, employees must be able to connect to the air supply system in a "clean" environment while donning protective equipment prior to entering the containment room.

According to ANSI Standard Z87.1-1989 (Practice for Occupational and Educational Eye and Face Protection), "faceshields are secondary protectors and shall be used **only** with primary protectors." Therefore, we recommend that employees should be required to wear safety glasses/goggles even when faceshields are being worn.

Training

An ongoing safety awareness program should be implemented to maintain a high level of interest and awareness of safety over extended periods of time.

Even if the appropriate engineering controls are in place, and supervisors have trained their workers thoroughly and continue to enforce safe work practices, an awareness program is still necessary to maintain interest in safety.

While written training policies met the appropriate regulatory requirements, many employees did not appear to understand general infection control principles (i.e., use of gloves while handling contaminated clothing). Additional hazard communication training should be offered regarding task-specific duties. For example, employees should be shown the order in which to remove contaminated clothing after exiting the containment room. Employees should also be instructed on proper spill response training including who to contact, what PPE to wear, and how to decontaminate the area. This process should help the supervisor better understand the jobs he or she supervises.

Employees should receive additional training regarding the use, care, and storage of respirators. Stericycle should ensure the integrity of respirators being worn (NIOSH investigators observed a hole in one of the supplied-air hoods) and that a sufficient number of supply air hoods are kept in stock at all times. Employees should not wear or re-use soiled PPE, including respirators. The use of appropriate respiratory protection for each job duty, including maintenance, should be reviewed. Maintenance employees must wear the appropriate clothing and respirators when entering the containment room prior to decontamination fogging (employees stated that respirators are often not worn and that some employees reportedly cut holes in their Tyvek suits to have access to their pockets). In addition, employees should always be encouraged to use appropriate PPE. Employees reportedly have been instructed to respond to spills without the use of respiratory protection.

Fire hazard safety training should be conducted for all employees, and in particular the RF oven operators. Carbon should be removed from vessels on a more frequent basis to prevent potential fire hazards.

Employee Access to the Containment Room

During the January site visit, NIOSH commented on the use of the change room and made recommendations consistent with current standards and guidelines for biohazard containment facilities.[35] The best way to set up clean and dirty change rooms with respect to a zone of contamination is to have one-way flow. An airlock should have adequate space if used for gowning and ungowning, along with space for storage and disposal of gowns, masks, and gloves. Handwashing and eyewashing facilities must be provided and shower facilities should be considered, depending on the nature of the hazard. An example of an appropriately designed change room is presented in Figure 2.

With this type of design, employees would enter the change room through a corridor (section B) and pass into a clean room (section A). All doors should be self-closing. Un-used supplies and PPE would be stored in the clean room. Employees, after donning the appropriate equipment, would enter the containment room by passing back through the corridor (first through section B, then through section C). After working in the containment room, employees would exit the processing area by entering into the corridor (section C) and passing directly into a decontamination area (section D). The decontamination area should contain eye and handwash stations as well as an area for employees to disinfect their boots and an area to dispose of contaminated clothing. Employees would then enter a shower area which would pass directly through to the clean room (section A). This type of design would prevent the cross-contamination of areas and materials.

Work Practices

Since validation studies for the Stericycle process regarding the inactivation of infectious waste are based on reaching a temperature of 95°C, all locations probed within the vessel should reach this minimum temperature. Stericycle should consider automating the process of measuring and recording

the temperatures within the vessels. The process could automatically designate which vessels needed to be re-cooked.

Employees should be trained to move no more than three bins at a time to prevent accidents and spills from occurring. Several employees reported being splashed in the face when unloading the bins either because fluids had spilled on top of the lids or the lids of the tubs were not secure.

Stericycle should develop a written protocol outlining the steps to be taken and the types of personal protective equipment to be worn in the event of a shut down in the Stericycle waste treatment process (as occurred in March 1997). Employees should be trained regarding these procedures to ensure their understanding of the correct protocol to be followed.

Due to the hazards present in the containment room, as well as high noise levels, radios (or other communication devices) should be provided for those entering the room.

Maintenance

HEPA filters should be leak-tested on a semi-annual basis or when any changes occur. Filters should never be removed from the process flow and should not be cleaned with compressed air since this may compromise their integrity.

A log should be kept of all maintenance activities and repairs to equipment and a written preventive maintenance program should be developed and implemented.

The manufacturer of the oven recommends that tubes should be rotated every 500 to 1,000 working hours. In addition, all components should be kept clean in order to function appropriately.

Treatment of Waste by Stericycle Laboratory Customers

Stericycle should require laboratory facilities to decontaminate infectious cultures prior to disposal. This would reduce the risk posed to the facility employees as well as to those transporting and processing the waste. The importance of this has been stressed in the CDC/National Institutes of Health (NIH) guidelines for microbiological and biomedical laboratories.[35] According to these guidelines, a method for decontaminating waste should be available, preferably within the laboratory (e.g., autoclave, chemical disinfection, incineration, or other approved decontamination method).

OSHA incorporated the CDC/NIH guidelines in their Proposed Rule on Occupational Exposures to Tuberculosis.[37] OSHA's proposal requires that a method of decontamination of waste contaminated with Mtb shall be available in or as near as feasible to the work area [paragraph (e)(2)(iv)]. Both NIOSH and the Washington State Department of Labor and Industries (WISHA) have stated their support for this provision because it will minimize exposures of medical waste treatment workers to viable Mtb.[38,39]

Ventilation

A supplemental ventilation system should be added to the in-feed chute to maintain at least 2,000 CFM ventilation flow rate through the in-feed chute, even if the process line would completely clog. Additional enclosures should be added around the in-feed chute opening to restrict the area from which the in-feed chute can draw air. This should reduce air currents across the face of the in-feed chute, thereby reducing the escape of contaminants trapped in the wake formed behind the Steritubs as they are withdrawn from the mouth of the in-feed chute. If possible, an automated dumping mechanism should be installed which would allow the opening of the in-feed chute to be completely enclosed. Such a

device would have to be carefully designed so as to not create any additional ergonomic hazards.

Changes in Work Practices and Process Equipment

During the course of the NIOSH evaluation, several changes were noted, including the following:

- The swinging doors previously located at the vessel re-load entrance to the containment doors were replaced with plastic strips. According to employees, these doors were difficult to open and shut, and on occasion, were left open.
- A steam cleaner was purchased to clean the plant floor.
- The containment room pit was being steam-cleaned prior to decontamination fogging.
- The plant was currently running one shift per day instead of two.
- All surfaces in the pit of the containment room were re-painted.
- The joints of the ductwork in the containment room were sealed with duct tape.
- According to employees, the section of ductwork leading into the secondary shredder was replaced.
- The airline hoses for the supplied air line respirators were changed to a larger diameter.
- Torit™ filters were no longer being stored in the pit of the containment room.
- A large storage tank was placed in the pit of the containment room to collect waste from the process.

Some of the above changes in the process will need to be reviewed by the appropriate agencies based on operating conditions listed in the permit.

Records unavailable for NIOSH review, including maintenance logs for the operation of the RF oven, cleaning the RF bulbs, for the calibration of the temperature probes used for the vessels and maintenance records ("nightly cards") kept daily by the electricians should be reviewed by the appropriate state agencies.

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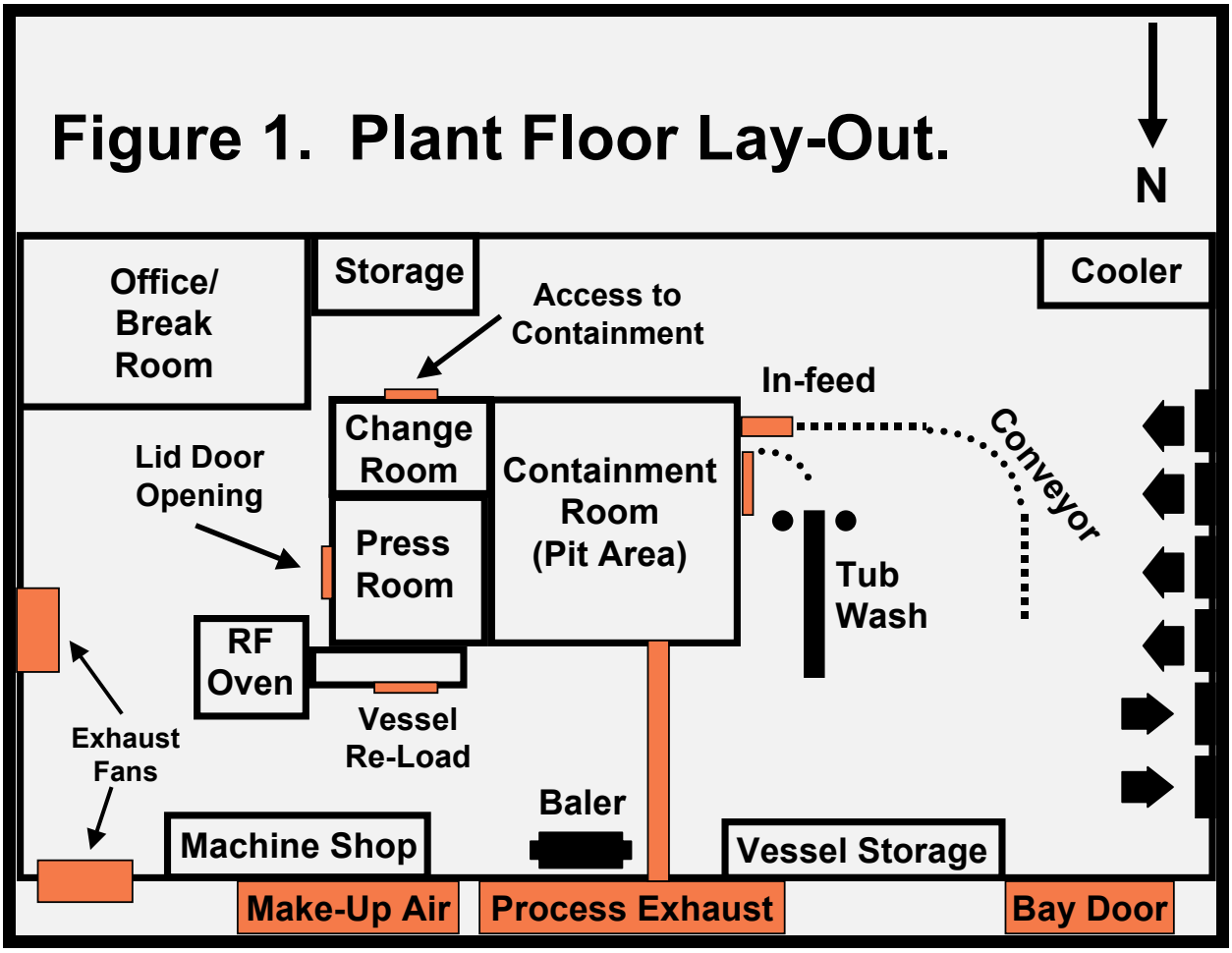
Figure 1. Plant Floor Lay-Out.
N
Office/
Break
Room
Storage
Access to
Containment
Cooler
In-feed
Change
Room
Containment
Room
(Pit Area)
Conveyor
Lid Door
Opening
Press
Room
Tub
Wash
RF
Oven
Exhaust
Fans
Vessel
Re-Load
Baler
Machine Shop
Vessel Storage
Make-Up Air
Process Exhaust
Bay Door

Figure 2. Example of Change Room.

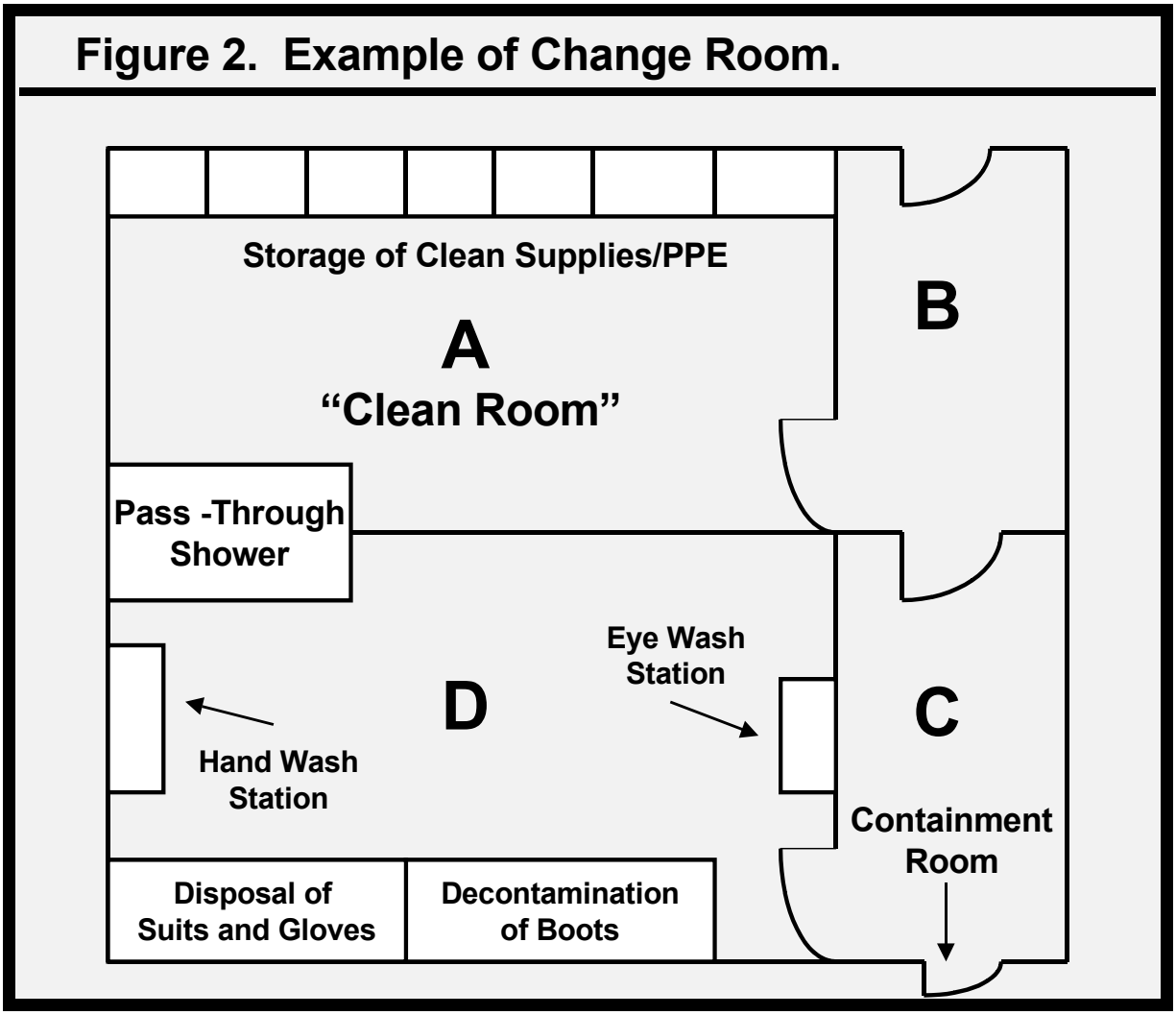

Table 1
Time (in seconds) for tracer gas to appear at the monitoring location relative to when it appeared at the vessel reload opening
Stericycle, Inc.
Morton, Washington

Tracer Gas Release Site	Safety Cabinet	Oven Opening	Lid Door	Overhead Door	Reload Opening	Make-up Air
Inside top of in-feed chute*	-49	-42	-29	-24	0	-9
Inside top of in-feed chute*	-49	-22	-29	-24	0	-21
Inside top of in-feed chute	-9	18	1	-24	0	-9
Inside top of in-feed chute	11	18	1	-24	0	31
Deep in in-feed chute	-9	38	21	-34	0	-9
Deep in in-feed chute	21	48	41	-24	0	31
Deep in in-feed chute	118	35	12	**	0	-22
Inside open overhead door	1	28	21	86	0	41
Inside open overhead door	9	25	12	74	0	18

*** denotes existence of a leak from a control valve of a NIOSH tracer gas cylinder in the passageway along the south wall of the containment room for the duration of the injection.**
**** data not available due to datalogger failure.**

Table 2
Time (in seconds) for tracer gas to reach peak value after it appeared at the monitoring location
Stericycle, Inc.
Morton, Washington

Tracer Gas Release Site	Safety Cabinet	Oven Opening	Lid Door	Overhead Door	Reload Opening	Make-up Air
Inside top of in-feed chute*	10	50	40	30	130	210
Inside top of in-feed chute*	10	80	80	60	150	150
Inside top of in-feed chute	110	140	180	80	110	170
Inside top of in-feed chute	110	210	190	80	130	250
Deep in in-feed chute	90	100	120	60	60	80
Deep in in-feed chute	90	110	110	80	90	100
Deep in in-feed chute	80	90	120	**	40	80
Inside open overhead door	60	80	110	80	60	50
Inside open overhead door	80	90	110	230	70	60

*** denotes existence of a leak from a control valve of a NIOSH tracer gas cylinder in the passageway along the south wall of the containment room for the duration of the injection.**
**** data not available due to datalogger failure.**

Table 3
Ratio of the height of the tracer gas concentration peak relative to the peak height at the vessel reload opening.
Stericycle, Inc.
Morton, Washington

Tracer Gas Release Site	Safety Cabinet	Oven Opening	Lid Door	Overhead Door	Reload Opening	Make-up Air
Inside top of in-feed chute*	8.3	4.8	16.8	2.0	1.0	1.3
Inside top of in-feed chute*	6.3	7.8	20.4	2.6	1.0	1.7
Inside top of in-feed chute	3.2	0.7	0.8	2.3	1.0	0.8
Inside top of in-feed chute	3.9	0.8	0.9	2.4	1.0	0.9
Deep in in-feed chute	1.5	0.6	0.6	1.2	1.0	0.5
Deep in in-feed chute	1.4	0.5	0.7	1.4	1.0	0.4
Deep in in-feed chute	9.4	0.3	0.5	**	1.0	0.9
Inside open overhead door	3.6	0.5	0.6	0.2	1.0	0.5
Inside open overhead door	3.5	0.6	0.6	0.2	1.0	0.7

*** denotes existence of a leak from a control valve of a NIOSH tracer gas cylinder in the passageway along the south wall of the containment room for the duration of the injection.**
**** data not available due to datalogger failure.**

Table 4
Air Sampling for Culturable Bacteria
Stericycle, Inc., Morton, Washington
Sampling Dates: January 27 - 29, 1998

Sample Numbers[a] (Sampling Date)	Location (Sampling Time)	MacConkey Agar	Mannitol Salt Agar
		Taxa (CFU/m^3)[b]	Taxa (CFU/m^3)[b]
4 - 6[c] (1/27/98)	Press Room - In Containment (9:10)[d]	Total GNR* (140)	Total Bacteria (43)
55 - 57 (1/28/98)	Press Room - In Containment (12:01)	*P. aeruginosa* (4) Total GNR (7)	*S. aureus* (29) Total Bacteria (100)
76 - 78 (1/29/98)	Press Room - In Containment (8:14)	*E.coli* (102) Total GNR (23)	*S. aureus* (165) Total Bacteria (233)
19 - 21 (1/27/98)	In-Feed Station (12:50)	Total GNR (2)	Total Bacteria (23)
42 - 44 (1/28/98)	In-Feed Station (8:21)	No Growth	Total Bacteria (14)
65 - 67 (1/29/98)	In-Feed Station (6:15)	Total GNR (13)	Total Bacteria (204)
1 - 3 (1/27/98)	Pit In Containment - Between Shredders (8:35)[d]	Total GNR (2)	*S. aureus* (16) Total Bacteria (36)
52 - 54 (1/28/98)	Pit In Containment - Between Shredders (11:15)	*P. aeruginosa* (2) Total GNR (11)	*S. aureus* (7) Total Bacteria (41)
79 - 81 (1/29/98)	Pit In Containment - Between Shredders (8:31)	*E.coli* (7) Total GNR (16)	Total Bacteria (93)
22 - 24 (1/27/98)	Tub Wash Station (13:18)	Total GNR (2)	Total Bacteria (9)
39 - 41 (1/28/98)	Tub Wash Station (8:00)[e]	Total GNR (2)	Total Bacteria (66)
68 - 70 (1/29/98)	Tub Wash Station (6:36)	Total GNR (13)	Total Bacteria (131)
11 - 14 (1/27/98)	Office Reception Area (11:15)	No Growth	Total Bacteria (10)
32 - 34 (1/28/98)	Office Reception Area (6:34)	No Growth	Total Bacteria (8)
85 - 87 (1/29/98)	Office Reception Area (12:16)	No Growth	Total Bacteria (88)

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Sample Numbers[a] (Sampling Date)	Location (Sampling Time)	MacConkey Agar	Mannitol Salt Agar
		Taxa (CFU/m^3)[b]	Taxa (CFU/m^3)[b]
7 - 9 (1/27/98)	Change Room (10:50)[d]	*P. aeruginosa* (2) Total GNR (7)	Total Bacteria (23)
58 - 60 (1/28/98)	Change Room (12:28)	No Growth	Total Bacteria (23)
82 - 84 (1/29/98)	Change Room (8:56)	Total GNR (2)	Total Bacteria (25)
16 - 18 (1/27/98)	Loading Dock (12:15)	No Growth	*S. aureus* (1) Total Bacteria (4)
45 - 47 (1/28/98)	Loading Dock (8:49)	No Growth	Total Bacteria (15)
62 - 64 (1/29/98)	Loading Dock (5:55)	Total GNR (2)	Total Bacteria (57)
25 - 27 (1/27/98)	Vessel Re-Entry Doors (13:46)	No Growth	Total Bacteria (7)
36 - 38 (1/28/98)	Vessel Re-Entry Doors (7:27)	Total GNR (2)	Total Bacteria (13)
73 - 75 (1/29/98)	Vessel Re-Entry Doors (6:53)	Total GNR (1)	Total Bacteria (34)
28 - 30 (1/27/98)	Outdoor Air - By Office Entrance (14:57)	No Growth	Total Bacteria (3)
48 - 50 (1/28/98)	Outdoor Air - By Office Entrance (10:16)	No Growth	No Growth
89 - 91 (1/29/98)	Outdoor Air - By Office Entrance (12:40)	No Growth	No Growth

[a] Concentrations are based on an average of the sample numbers listed.
[b] CFU/m^3 = Colony forming units per cubic meter of air.
[c] Press operator was cleaning work area with compressed air during the collection of sample #6.
[d] Process was not operating during the collection of the sample due to a clog in the system.
[e] Since the RF oven was not operating until 8:10 a.m., processing was slow at this work station.
*GNR = Gram negative rod.

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