A TUBERCULOSIS OUTBREAK AMONG MEDICAL WASTE WORKERS

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ABSTRACT

Occupational exposures to Mycobacterium tuberculosis and bloodborne pathogens were evaluated during the processing of medical waste at a commercial treatment site. The facility utilized a method consisting of shredding waste followed by disinfection with dielectric heat. A previous epidemiologic investigation revealed three employees with active tuberculosis, the etiologic agent in each case having a different drug susceptibility pattern. This finding eliminated the possibility of person-to-person transmission between employees. Further evaluation confirmed that one employee was infected with a strain of M. tuberculosis identical to an isolate recovered from a patient treated at a clinic that sent waste to the treatment facility. Factors contributing to exposures included: the aerosolization of products contained in the waste, deficiencies in the facility design, absence of safety policies, inadequate design and operation of processing equipment. Furthermore, misunderstandings among employees regarding equipment operating procedures, use of personal protective equipment, and routes of disease transmission may have also been involved in employees exposures.

BACKGROUND

Process Description

A heating process referred to as electrothermal deactivation (ETD™) is utilized by the facility to inactivate microorganisms contained in medical waste (Turnberg, 1996). The process uses low frequency (64 MHZ) radiation with 15-foot wavelengths and an electrical field strength of 50,000 volts per meter. 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. A total of five ETD™ facilities were in operation in the United States at the time of the investigation.

The RF heating system (oven) employed in the ETD™ process is manufactured by a company other than the one which operates the treatment facility. Traditional dielectric applications include processing (drying) textiles, plastics, ceramics, rubber, wood, food, and other non-conducting materials. The manufacturer makes no claims as to the effectiveness of their oven for the inactivation of infectious microorganisms. Rather they only stipulate that their oven can heat materials to a specified temperature.

The facility began operating in January of 1992, receiving waste from clinical laboratories, hospitals, and medical/dental clinics located in Washington, Idaho, Oregon, and British Columbia. The types of waste which are processed consist of the following: cultures and stocks of infectious agents and associated biologicals: liquid human waste, including blood, blood products, and body fluids; sharps; and small amounts of human pathological waste if mixed with other categories of medical waste. The facility does not treat chemotherapeutic, pathological, radioactive, anatomical (except as noted above), or chemical waste.

The processing plant consists of a 13,500-square-foot area with a 800-square-foot, two-story steel-walled containment room in the center of the

INTRODUCTION

At the request of Washington State’s Departments of Labor and Industries (L&I) and Health (DOH), the National Institute for Occupational Safety and Health (NIOSH) evaluated the potential for occupational exposures to M. tuberculosis and bloodborne pathogens from the processing of medical waste at a commercial treatment site. (NIOSH, 1998a). Events leading to this request for technical assistance involved an outbreak of suspected occupationally-related tuberculosis among employees. An initial site visit was conducted November 18-20, 1997 with a subsequent evaluation being performed on January 26-29, 1998.
plant floor. The containment area includes these areas: (1) a change room where employees don and remove protective clothing and equipment worn in the containment room; (2) a “press room” in which 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).

Incoming medical waste is received on trailers in either plastic containers with snap-on lids or cardboard boxes. Cardboard boxes (which contain anatomical waste) are placed in a cooler until they can be transported to an incinerator. Containers are unloaded from the trailers by manually placing them on a hand truck and transporting them to a powered conveyor leading to the in-feed station. Containers are then manually emptied into the in-feed chute and placed on another conveyor to be delivered to a wash station. The in-feed station operator is responsible for unclogging the system which requires the individual to enter the containment area to access the primary and secondary shredders in the pit. At the wash station, containers are placed upside down over a pressure wash nozzle while employees (two per shift) scrub the outside of the container with a sponge. Containers are sanitized with hot water (maintained at 180°F) and a mild surfactant. The water at the wash station is recycled and used to wet shredded waste inside the containment room.

Processing equipment inside the containment room shreds the waste and then blows it through the ducted-system to fill vessels with approximately 500 pounds of waste. Shredded waste is compacted in the vessels by the press operator with a hand-operated hydraulic press. While the waste is being compacted, the operator distributes the waste uniformly throughout the vessel and sprays the waste with water to achieve a 10 to 15 percent moisture content. Vessels are manually capped and guided to a conveyor that delivers them to the RF oven for decontamination. Processed vessels exit the oven and are probed to determine their core temperature. A homogenous temperature of 95°C is required throughout each vessel exiting the oven to ensure the inactivation of organisms. If a temperature of 95°C is not achieved in any part of the vessel, the container is re-processed by placing it back into the oven through the vessel re-entry door. Processed waste is hauled from the facility by truck to a landfill.

At the time of the NIOSH site visit, exhaust air from the oven area was being recirculated into the containment room. Exhaust air from the containment room passes through a series of filter banks including 36 Torit™ filters, 16 Mark 80 filters, and 16 final high-efficiency particulate air (HEPA) filters.

The company conducts efficacy testing as recommended by the State and Territorial Association.
on Alternate Treatment Technologies (STAATT), to
demonstrate a 6-log_{10} inactivation or greater of
vegetative bacteria, fungi, lipid/nonlipid viruses,
parasites, and mycobacteria, and a 4-log_{10}
reduction or greater in the concentration of viable
B. steaothermophilus or B. subtilis spores (STAATT,
1994). Results from these studies were used to ob-
tain an operating permit for the facility.

The facility operated one production shift per
day at the time of the NIOSH site visit. Two work
crews, each consisting of 13 employees, alternated
work days. Approximately 2,300 pounds of waste
per hour (lbs/hr) were being processed at the time,
while the maximum production rate allowed by the
county health department was 6,000 lbs/hr.

Employees working on the plant floor wore
N95 filtering facepiece respirators, coveralls, hear-
ing protection, impervious gloves and boots, and
safety glasses. The use of N95 respirators was a
new practice implemented as a result of the tuber-
culosis outbreak. In addition to the personal pro-
tective equipment (PPE) mentioned previously, in-
feed station operators wore safety lines and face
shields. Employees entering the containment area
wore Tyvek suits, impervious shoes and gloves,
and airline respirators with loose-fitting hoods.
All clothing items were 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 sug-
gested stopping this practice because medical
waste workers were not considered at high risk for
tuberculosis.

PREVIOUS INVESTIGATIONS

Washington Department of Health (DOH)
Epidemiologic Investigation

From May through September of 1997, three
cases of active tuberculosis in current or recent for-
mer employees of the facility were reported to the
DOH. This was considered to be an outbreak be-
cause of the relatively low numbers of active tuber-
culosis cases in the State of Washington at that
time. In 1997, Washington State had a tuberculosis
incidence rate of 5.4 cases per 100,000 persons
(Washington State DOH, 1996), which was less
than the national tuberculosis rate of 7.4 cases per
100,000 persons (CDC, 1998a). Furthermore, mul-
tidrug-resistant M. tuberculosis isolates (resistant to
at least isoniazid and rifampin) are uncommon in
Washington State. Five or fewer cases were re-
ported annually during 1992-1997 (Washington
State DOH, 1996).

The DOH’s epidemiologic investigation re-
vealed that isolates of M. tuberculosis recovered
from each of the three employees had a different
drug susceptibility pattern. This finding eliminated
the possibility of person-to-person transmission be-
tween employees. Further evaluation confirmed
that one employee was infected with a strain of M.
tuberculosis identical to an isolate recovered from
a patient treated at a clinic that sent waste to the
facility (Johnson, et al, 2000). The three employees
worked at the following locations: tub wash sta-
tion, in-feed station, and press room (Figure 1).

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

In response to an employee complaint alleging
occupational exposure to M. tuberculosis 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
treatment process was conducted, and all employ-
ees were interviewed.

The inspection report indicated that a safety
flap had been missing from the in-feed chute open-
ing for at least two years. This flap was designed to
prevent waste from being thrown back onto the
plant floor in the event of a clog in the shredding
equipment. Employees reported to L&I that the sys-
tem lost negative pressure when the shredders be-
came clogged, resulting in a reversal of air flow (air
escaped from the in-feed chute to the plant floor),
referred to by employees as “blowback.”

As a result of the L&I investigation, the facility
was cited for “exposing its employees to hazard-
ous concentrations of biological agents which may
arise from the processing, handling, or using of
waste.” Factors resulting in this citation included:
failure to require employees to shower at the end
of their shift, to thoroughly decontaminate their
shoes in the change room after exiting the process
area, and to wear their face-shields in the down po-
sition at all times. The facility was also found to
have failed to supervise and enforce its accident
prevention program. Two additional general cita-
tions were issued for failure to keep an Occupa-
tional Safety and Health Administration 200 log
and summary of occupational injuries and illnesses
(OSHA 200 logs).
NIOSH INVESTIGATION

Medical Evaluation Methods

During the follow-up visit, NIOSH representatives privately interviewed six out of the 22 employees who were working that week. While all employees were notified of the NIOSH visit and were invited to participate in the interviews, only six employees volunteered to be interviewed. Interviews were informal discussions with the employees about their health and work practices. The OSHA 200 logs, available medical records for employees who reported occupational injuries or illnesses either directly to NIOSH or on the OSHA 200 logs, and training materials were reviewed. The previously conducted epidemiologic investigation was discussed with representatives from the DOH.

Environmental Evaluation Methods

Airflow Visualization

Smoke tubes and theatrical fog were used to visualize airflow patterns. Smoke from glass tubes about the size of a ball point pen was released at several locations inside the plant, and the direction and velocity of the smoke was observed. For example, smoke tubes were used to evaluate airflow in and out of the plant at doorways, to observe airflow patterns within the containment room, and to investigate negative pressure at the face of the infeed station.

For larger areas, the release of theatrical smoke was used to determine if there were any visible leaks from the containment room, and to determine whether air at the face of the in-feed chute was captured by the exhaust ventilation of the containment room. Smoke was also released outside the building where the containment room air was exhausted to determine whether this air traveled back into the plant.

Pressure Monitoring

Pressure measurements were performed with micro-manometers capable of measuring pressure as low as 0.001 inches of water. The difference in pressure with respect to the main plant area was monitored at the following three locations: the in-feed chute, the containment room, and just inside the vessel re-load opening (Figure 1). The in-feed chute was monitored with the pressure port located in three different positions. Data-logging was utilized to store sampling data and to generate a sampling report.

Tracer Gas Evaluation

While chemical smoke was used to visualize air movement in the vicinity of a chosen location, a different type of marker was needed to quantify air distribution. Tracer gases are useful for tracking the potential transport of agents that cannot themselves be monitored efficiently due to their low concentrations, sporadic release, and/or unavailable detection methods. Therefore, sulfur hexafluoride, a colorless, odorless, nonflammable gas measurable at concentrations less than one part per million (ppm) was used to determine the potential for spread of airborne infectious agents. Having few industrial applications other than the manufacturing of electrical circuit devices, it is an ideal gas for detecting leaks and assessing the dispersion of pollutants (Kroschwitz and Howe-Grant, 1994).

In this study, tracer gas was used to determine if there were any leaks or emission points from the processing area and if there was re-entrainment of exhausted air back into the building. The following seven sites were selected to be monitored with MIRAN 203 infrared analyzers for the appearance of tracer gas: above the in-feed chute opening, between the entrance of the containment room and the office area, above the lid door opening, outside the edge of the vessel re-load door, above the RF oven opening, at a supply opening for make-up air, and inside the open doorway on the north side of the building (Figure 1). In addition, 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 ducted process line into the containment room itself and to monitor tracer gas concentrations passing through the building exhaust fans.

The tracer gas studies were conducted in ten 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 grouping of four releases from a tracer gas injection port positioned inside the in-feed chute opening, just below the bottom edge.
For the first grouping of four releases of tracer gas, the control valve of the tracer gas cylinder was, unknown at the time, leaking prior to 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. Two of the injections with the leak were analyzed because they provided useful data. After the leak in the control valve was discovered, the valve was removed from the injection line, and there were no leaks for the 14 subsequent injections.

The sixth grouping consisted of two releases just inside the open overhead door on the north side of the building. Another grouping consisted of two releases into the containment room and two groupings involved the release of tracer gas into the press 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**

Fluorescein dye has been used previously to demonstrate the generation of aerosols and leakage from laboratory equipment during routine procedures (Collins, 1988). A dilute fluorescein dye solution, placed in 130 milliliter (mL) plastic specimen containers, was used to spike the contents of the waste containers. Sealed containers of dye were added to the containers as the in-feed station operator removed the lid prior to dumping the contents into the in-feed chute.

To assess the presence of airborne fluorescein dye, area air samples were collected with Teflon® filters in closed-face, 37-mL cassettes 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 containers were being spiked. Air samples were collected over a two-day period from the following locations on the plant floor: the opening of the in-feed station, approximately four feet from the in-feed station; in a hallway approximately 12 feet from the in-feed station on the south wall; the tub wash station; the entrance to the change room; the door leading to the cafeteria; the exit of the RF oven; the bay door on the north side of the building; inside a truck being loaded with treated waste; and the face of the vessel re-entry doors. Inside the containment room, samples were collected in the change room, the pit area, and the press room. A control sample was collected in the office.

**Bioaerosol Sampling**

To determine the concentrations of culturable airborne bacteria, a 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. Duplicate air samples were collected over a three-day period to recover bacteria on either MacConkey agar (Gram-negatives), or Mannitol Salt agar (Gram-positives). Only *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus* were specified. Since these bacteria are routinely associated with medical waste streams, they were used as indicators of whether or not aerosolization of the waste was occurring. 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.

Bioaerosol evaluation criteria do not exist for the assessment of what would be considered “safe” for workers processing medical waste. However, sampling results can provide useful data by allowing the comparison of the concentrations of bacteria and predominant species of organisms found in suspect exposures sites with samples collected at control locations. For example, the seven sample locations (potential emission points) chosen at the facility included: 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. It was anticipated that the concentrations of organisms associated with medical waste would be the highest inside the processing area (press and containment rooms). As previously described, the shredding and compacting process is carried out in an enclosed area which is operated under negative pressure. Control sample locations included the office reception area, and outside near the main entrance to the building.

**GUIDELINES FOR CONTROLLING OCCUPATIONAL TRANSMISSION OF TB**

Specific criteria for evaluating the risk of tuberculosis transmission in medical waste treatment fa-
facilities do not exist. However, the following basic approaches have been recommended to reduce the potential risk of tuberculosis transmission in health care settings (CDC, 1994): (1) prevent infectious particles from entering the air by providing rapid identification, isolation, and treatment of persons with active tuberculosis; (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 of appropriate respiratory protection in areas where there is still a risk of exposure to M. tuberculosis; and (4) use of TST screening to identify persons with tuberculous infection, and provide preventive treatment (or treatment of active tuberculosis) when appropriate.

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 were uncertain about the order in which to put on and remove PPE, and reported that they had been discouraged from using PPE during spill responses in the production area.

A total of 31 medical records of both current and former employees were reviewed. These 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 virus (HBV) vaccine, and of these, few employees were tested for antibody to HBV surface antigen after receiving the three-dose vaccine series or after incurring a needlestick or other sharp object injury.

Review of OSHA 200 logs showed differences in the number of needlesticks listed on the logs and those in the medical records. NIOSH found five OSHA 200 log reports of needlesticks of which three were not indicated in the medical records. Conversely, NIOSH discovered five reports of needlesticks in the medical records that were not listed in the OSHA 200 logs. This indicated that some needlestick injuries were not reported/ documented, and that not all were followed up with medical care.

Environmental Evaluation

Respiratory Protection

During the initial site visit, NIOSH investigators detected odors in the containment area while using the company-supplied airline respirators with loose-fitting hoods. Several employees reported detecting odors using the same airline respirator system. According to the minutes from safety meetings, problems had been identified with the airline respirator system as early as May of 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 back-up respirators had not been satisfied; one of the hoses for the airline respirator was in need of repair; and concerns that the supply air compressor was not providing enough pressure had not been addressed. An internal memo written by management representatives 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 would not stay unrolled unless someone held the hose. Therefore, it was concluded that only one person could “safely” work in this area at a time.

During the January follow-up visit, 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 NIOSH approval. Since some of the replacement parts were not selected from those included on the NIOSH approval list (TC-19C-154), they had not been adequately evaluated as part of the system.

Disposable N95 respirators were being worn on the plant floor by all employees at the time of the initial NIOSH site visit. Since no new positive tuberculosis skin tests had been found among current employees, management decided in mid-December that respirators were no longer needed on the plant floor. This was in opposition to a letter issued by L&I which stated that the “use of appropriate respirators within the plant was a necessary measure to protect against future exposure, at least
until the specific methods of transmission could 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 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 became wet due to the steam generated during this process (the worker's face was 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 and press rooms were to remain closed. To enter the containment room, employees passed through a "change room," where protective clothing was stored. This room was inappropriately used as both a "clean" change room (storing of protective clothing) and a "dirty" change room where contaminated clothing was removed and discarded. Eye and hand wash stations were not available inside this area. On several occasions during the NIOSH site visit, both doors of the change room (one leading from the plant floor into the room and one leading from the room into the containment area) 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).

Soiled, disposable Tyvek suits were being reused by employees. 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, but such waste bags were not present. Upon re-entering the change room, employees would "shake out" the used Tyvek suits thus potentially aerosolizing infectious agents. In addition, gloves were not worn while handling the soiled Tyvek suits, and the interior necklines of most of the hoods were heavily soiled.

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 potentially expose the wearer to infectious aerosols.

**Occurrence of "Blowback"**

According to employee safety meeting minutes, the occurrence of "blowback" was documented at the facility as early as June of 1995. Employees reported during the first site visit 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 blowback 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, blowback occurred when the primary shredder became clogged. At that time, 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.

**Training**

While written training policies met the appropriate regulatory requirements, many employees did not understand general infection control principles, the potential hazards associated with the infectious waste processed at the facility, or 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. Employees reported that, although they received training on the appropriate clothing to wear while in containment, they had not been instructed on how to remove and discard of the contaminated materials. Employees also expressed concern regarding appropriate spill response training, and there was confusion among employees regarding the appropriate PPE to be worn in the event of an accident or spill. According to employees and confirmed by our observations, employees were asked to perform jobs for which they had not received adequate training. For example, one employee was required to switch from the tub wash area to the in-feed station even though the employee had never performed this job. In addition, inconsistencies were identified during discussions with management representatives regard-
ing training requirements among their ETD™ facilities. For example, "safety tests," which were required at the other ETD™ facilities as part of employee training, reportedly had not been administered to employees at the investigated site.

**Work Practices**

Company policy required a homogenous temperature of 95°C in each treatment vessel after it exited 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, a vessel caught fire during removal and 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 such a hazard.

The company’s operating plan stated that in the event the treatment process would shut down, all waste was to be sent to their area incinerator facility. The operating plan, however, did not specifically state how this should be accomplished. According to employees, on one such occasion, they were instructed to manually remove infectious waste from the containers and place it into cardboard boxes for incineration.

Exhaust air from the RF oven was originally exhausted outdoors, but due to odor complaints from the community, the facility changed the process to recirculate the exhaust to the containment room. This change reportedly occurred approximately two years prior to the NIOSH 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 the 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) versus the previously used filters.

The incentive pay system was based on the number of containers processed in excess of 1,260 per shift. This may have contributed to employees overlooking or bypassing safety-related practices and procedures. For instance, employees reported that Torit™ air filters were removed from the filter bed of the treatment process exhaust ventilation when they became clogged or wet because it would slow the process down. However, instead of maintaining a readily available stock of new filters at the facility, employees were instructed to remove, but not replace, several of the filters from the filter bed. Another method reportedly employed to treat waste at a faster pace involved removing “un-cooked” vessels from the containment room through the vessel re-load doors.

Used Torit™ filters were reportedly stored in the pit of the containment room and cleaned with compressed air, but the manufacturer’s specifications state that the filters should be cleaned by “pulse cleaning” or with water. The specifications also stated that a lower filtration efficiency may result from cleaning them with water (they must be dried thoroughly before reinstallation). Employees reported that the HEPA filters had 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, could invalidate their certification. 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 were reportedly changed every 6 to 12 months, they had not been leak tested since their installation.

**Airflow Visualization**

Smoke tests showed that air entered the plant through the make-up air opening and the overhead door on the north wall, and through the loading dock doors on the west end of the building. Inside the facility, air generally flowed from west to east, with more going around the south side of the containment room than its north side. Air exited the building through the two exhaust fans in the northeast corner of the building.

Smoke released inside the containment room swirled around at a relatively high velocity, quickly dispersing. Eventually the smoke was exhausted
through the inlet to the filter auger fan and through openings on the inlet side of the primary and secondary mill fans. Within the containment area, air flowed from the press room down into the pit. No smoke was observed escaping the containment area onto the floor of the plant.

Smoke released outside the discharge of the containment room exhaust, on the north wall of the building, demonstrated that air could be blown down to, and in through the open overhead door on the northwest corner of the building. Winds were out of the east/southeast at the time of testing.

When smoke was released inside the in-feed chute, behind the plastic flaps, it was drawn down into the chute when waste was not being loaded. However, some smoke was caught in the wake formed around the waste container being pulled back from the in-feed chute after its contents had been dumped into the chute by the operator. A portion of this smoke escaped and flowed around the plant floor.

**Pressure Monitoring**

The pressure measured inside the containment room and just inside the vessel reload opening was negative with respect to the main area of the plant. However, there were six instances in which the negative pressure doubled in comparison to baseline levels. These pressure changes were most likely related to clogging of the shredders in the process line.

The pressure measured at the in-feed chute, just inside the flaps, was mostly negative, but 20 percent of the time on the second day of sampling, 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 indicated that during a clog, air from inside the flaps might have been discharged out of the in-feed chute.

The pressure measured deep inside the in-feed chute was always negative. On two occasions in which the pressure in the containment room became about twice as negative as normal, 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 tracer gas appearance and peak rise times, as well as the relative peak heights from six monitoring locations are presented in Tables 1, 2, and 3, respectively. These results were obtained from seven injections of gas into the in-feed chute and two releases just inside the open overhead door.

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 location. This site 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 at which tracer gas was detected at the safety cabinet, oven opening, and lid door opening were drastically different when there was no leak in the cylinder valve, indicating that these sites 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 (non-clogged) operation. In contrast, the times the gas was found at the make-up air location and overhead door indicated that these two locations were not in the path of the air movement from the leak in the cylinder valve. The relatively longer, more consistent times for the detection of the gas released at the overhead door indicated that air was being recirculated.

The rise times in Table 2 are the real time in seconds for the tracer gas to reach its peak concentrations after its initial detection at each of the monitoring locations. The shorter time intervals required for the gas to reach maximum concentration at the safety cabinet, oven opening, and lid door opening when there was no leak in the cylinder valve again indicated they were closer to the point of the leak from the cylinder valve than the make-up air and overhead door locations.

Since the quantity of tracer gas released would not be expected to be the same for each injection,
### Table 1
Time (in seconds) for tracer gas to appear at the monitoring location relative to when it appeared at the vessel reload opening.

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

* 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.

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

* 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.
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 a leak, again indicated they were close to the point of the leak. The much smaller ratios detected at the overhead door location after release from this site again support the suggestion that tracer gas reached this location after being recirculated.

**Fluorescein Dye**
Qualitative results were reported as a positive signal if fluorescein dye was present on the filter. Positive signals were observed for samples collected in the pit of the containment room, the press room, and at the in-feed station.

**Bioaerosol Samples**
The results of sampling for culturable airborne bacteria are presented in Table 4. The reported concentrations are averages of three 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. Sampling locations are listed in the table in decreasing order of overall concentrations of bacteria recovered in culture.

Bioaerosol concentrations in the press room were the highest. Total concentrations of both GNRs and Gram positive bacilli (including the three indicator organisms) ranged from 140 CFU/m³ on January 28 to 523 CFU/m³ on January 29. The process was not operating during the collection of the samples on January 27. All indicator organisms 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 positive bacilli) among these three areas (217 CFU/m³ at the in-feed station on January 29), was approximately half the highest concentration found in the press room. However, total airborne bacteria con-
<table>
<thead>
<tr>
<th>Sample Numbers (Sampling Date)</th>
<th>Location (Sampling Time)</th>
<th>MacConkey Agar</th>
<th>Mannitol Salt Agar</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 - 6 (1/27/98)</td>
<td>Press Room - In Containment (9:10)</td>
<td>Total GNR (140)</td>
<td>Total Bacteria (43)</td>
</tr>
<tr>
<td>55 - 57 (1/28/98)</td>
<td>Press Room - In Containment (12:01)</td>
<td>P. aeruginosa (4) Total GNR (7)</td>
<td>S. aureus (29) Total Bacteria (100)</td>
</tr>
<tr>
<td>76 - 78 (1/29/98)</td>
<td>Press Room - In Containment (8:14)</td>
<td>E.coli (102) Total GNR (23)</td>
<td>S. aureus (165) Total Bacteria (233)</td>
</tr>
<tr>
<td>19 - 21 (1/27/98)</td>
<td>In-Feed Station (12:50)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (23)</td>
</tr>
<tr>
<td>42 - 44 (1/28/98)</td>
<td>In-Feed Station (8:21)</td>
<td>No Growth</td>
<td>Total Bacteria (14)</td>
</tr>
<tr>
<td>65 - 67 (1/29/98)</td>
<td>In-Feed Station (6:15)</td>
<td>Total GNR (13)</td>
<td>Total Bacteria (204)</td>
</tr>
<tr>
<td>1 - 3 (1/27/98)</td>
<td>Pit In Containment - Between Shredders (8:35)</td>
<td>Total GNR (2)</td>
<td>S. aureus (16) Total Bacteria (36)</td>
</tr>
<tr>
<td>52 - 54 (1/28/98)</td>
<td>Pit In Containment - Between Shredders (11:15)</td>
<td>P. aeruginosa (2) Total GNR (11)</td>
<td>S. aureus (7) Total Bacteria (41)</td>
</tr>
<tr>
<td>79 - 81 (1/29/98)</td>
<td>Pit In Containment - Between Shredders (8:31)</td>
<td>E.coli (7) Total GNR (16)</td>
<td>Total Bacteria (93)</td>
</tr>
<tr>
<td>22 - 24 (1/27/98)</td>
<td>Tub Wash Station (13:18)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (9)</td>
</tr>
<tr>
<td>39 - 41 (1/28/98)</td>
<td>Tub Wash Station (8:00)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (66)</td>
</tr>
<tr>
<td>68 - 70 (1/29/98)</td>
<td>Tub Wash Station (6:36)</td>
<td>Total GNR (13)</td>
<td>Total Bacteria (131)</td>
</tr>
<tr>
<td>11 - 14 (1/27/98)</td>
<td>Office Reception Area (11:15)</td>
<td>No Growth</td>
<td>Total Bacteria (10)</td>
</tr>
<tr>
<td>32 - 34 (1/28/98)</td>
<td>Office Reception Area (6:34)</td>
<td>No Growth</td>
<td>Total Bacteria (8)</td>
</tr>
<tr>
<td>85 - 87 (1/29/98)</td>
<td>Office Reception Area (12:16)</td>
<td>No Growth</td>
<td>Total Bacteria (88)</td>
</tr>
<tr>
<td>7 - 9 (1/27/98)</td>
<td>Change Room (10:50)</td>
<td>P. aeruginosa (2) Total GNR (7)</td>
<td>Total Bacteria (23)</td>
</tr>
</tbody>
</table>
Table 4
Air Sampling for Culturable Bacteria

<table>
<thead>
<tr>
<th>Sample Numbers* (Sampling Date)</th>
<th>Location (Sampling Time)</th>
<th>MacConkey Agar Taxa (CFU/m³)b</th>
<th>Mannitol Salt Agar Taxa (CFU/m³)b</th>
</tr>
</thead>
<tbody>
<tr>
<td>58 - 60 (1/28/98)</td>
<td>Change Room (12:28)</td>
<td>No Growth</td>
<td>Total Bacteria (23)</td>
</tr>
<tr>
<td>82 - 84 (1/29/98)</td>
<td>Change Room (8:56)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (25)</td>
</tr>
<tr>
<td>16 - 18 (1/27/98)</td>
<td>Loading Dock (12:15)</td>
<td>No Growth</td>
<td>S. aureus (1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Total Bacteria (4)</td>
</tr>
<tr>
<td>45 - 47 (1/28/98)</td>
<td>Loading Dock (8:49)</td>
<td>No Growth</td>
<td>Total Bacteria (15)</td>
</tr>
<tr>
<td>62 - 64 (1/29/98)</td>
<td>Loading Dock (5:55)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (57)</td>
</tr>
<tr>
<td>25 - 27 (1/27/98)</td>
<td>Vessel Re-Entry Doors</td>
<td>No Growth</td>
<td>Total Bacteria (7)</td>
</tr>
<tr>
<td></td>
<td>(13:46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36 - 38 (1/28/98)</td>
<td>Vessel Re-Entry Doors</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (13)</td>
</tr>
<tr>
<td></td>
<td>(7:27)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>73 - 75 (1/29/98)</td>
<td>Vessel Re-Entry Doors</td>
<td>Total GNR (1)</td>
<td>Total Bacteria (34)</td>
</tr>
<tr>
<td></td>
<td>(6:53)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28 - 30 (1/27/98)</td>
<td>Outdoor Air - By Office</td>
<td>No Growth</td>
<td>Total Bacteria (3)</td>
</tr>
<tr>
<td></td>
<td>Entrance (14:57)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48 - 50 (1/28/98)</td>
<td>Outdoor Air - By Office</td>
<td>No Growth</td>
<td>No Growth</td>
</tr>
<tr>
<td></td>
<td>Entrance (10:16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>89 - 91 (1/29/98)</td>
<td>Outdoor Air - By Office</td>
<td>No Growth</td>
<td>No Growth</td>
</tr>
<tr>
<td></td>
<td>Entrance (12:40)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*a Concentrations are based on an average of the sample numbers listed.

*b CFU/m³ = 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 GNR = Gram negative rod.

f Since the RF oven was not operating until 8:10 a.m., processing was slow at this work station.

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 statistically significant). As was found in the press room, sample concentrations were significantly higher on January 29 at all three locations. The three indicator bacteria were cultured from the air in the pit of the containment room over the three-day sampling period, but were not identified in the samples collected from the in-feed and tub wash stations. Escherichia coli was cultured from the press room and the pit. Concentrations of total bacteria were consistently higher on January 29 at seven of the nine 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 site. Sam-
amples collected outdoors revealed the lowest con-
centrations (3 CFU/m³ was detected on January
27, while no growth was observed on January 28
and 29).

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

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 were three situations that could result
in ventilation problems: (1) dumping waste from
the containers into the in-feed chute; (2) clogging
of the process line; and (3) re-entrainment of ex-
haust air from the containment room.

Dumping of the Waste

There was a reduction in total airflow through
the in-feed chute when waste was being dumped
from the containers. This activity caused a disrup-
tion in airflow due to the presence of the waste
container in the mouth of the in-feed chute. The
wake formed behind the container could create a
negative pressure zone which could pull air from
the in-feed chute back out into the plant as the
container is removed by the operator.

Clogging of the Process Line

When there is a clog, the flow of air through
the in-feed chute could be drastically reduced and
even stopped. During these times, bacteria and
other organisms or toxins present in the waste
could be aerosolized and escape 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 ob-
served 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. Under these circumstances, aero-
solized waste could remain suspended in the plant
air for an hour or more until completely removed
by the general ventilation. Theoretically, over 99
percent of a contaminant may be removed from a
room in an hour if the air is well-mixed at seven air
changes per hour. However, in most rooms, there
may be localized areas which are poorly ventilated
or in which 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, which would allow air to
enter through any open doorway, as well as
through cracks around doors, including the over-
head doors on the loading dock and anywhere that
building panels did not fit tightly. The primary
routes by which air from the process line could re-
enter the main part of the plant were through the
overhead door on the north side of the building
and the make-up air system, depending on the pre-
vailing winds. When the wind is from the east, ex-
hausted air could enter through the overhead door,
but when the wind is from the west, the 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.

Tracer gas results collected at the time of the
evaluation indicated that air in the containment
room did not escape into the main plant area un-
der normal conditions. Although tracer gas results
indicated that air from the process line escaped
into the containment room, eventually all the air in
the containment room was drawn into the process-
ing exhaust stream. In the containment room, air
was found to mix well.

When tracer gas was released inside the over-
head door (refer to Table 1), it was detected at the
overhead door in approximately two minutes. The
reappearance and time required could vary de-
pending on the direction and speed of the prevail-
ing 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 pri-
mary and secondary nil negative air fans were
rated at 7,000 CFM each. Since the latter fans are

83
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 indicated that the loads on these fans may be somewhat higher than expected by the designers.

Aerosolization of Waste

CDC recommends that laboratory waste be decontaminated prior to leaving the facility for disposal. A study further supporting this recommendation demonstrated that compaction of infectious waste could result in significant releases of bioaerosols into the environment (Emery, et al, 1992). Samples collected at the 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 contained similar concentrations of bacteria. 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 the containment area. 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, and (2) the presence of airborne organisms from the opening and washing of waste containers. The latter condition appears to be more likely, since the three indicator 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 were approximately two times greater than those collected from the control areas. Further evaluation needs to be conducted to determine the cause of the elevated concentrations of bacteria recovered on January 29 in comparison to samples from the previous two days. Potential reasons for the increase could have been due to higher production rates or variability in the types of waste.

The airborne fluorescein dye samples further indicated that the potential for aerosolizing medical waste components existed at the facility. Dye was present on all filter samples collected inside the containment area and on two filter samples collected at the in-feed station.

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 due to the varying specific heat of the contents. Although the press operator is responsible for creating a 10 to 15 percent moisture content within the treatment vessels, this activity was not monitored. Furthermore, moisture content is also affected by the presence of blood and body fluids. In addition, the RF operator did not consistently measure temperature in a predetermined number of locations to assess even heating throughout the vessels.

RECOMMENDATIONS

The following recommendations were provided to the facility and may be applicable at all facilities using the ETD™ process.

Treatment of Waste by Laboratories

The company should require their client laboratory facilities to decontaminate materials potentially contaminated with viable *M. tuberculosis* (e.g., cultures, stocks, or tissues) at the generation site prior to disposal. This would reduce the risk posed to the facility employees, as well as to those transporting and processing the waste. This recommendation is consistent with those provided by both the CDC/National Institutes of Health (CDC/NIH, 1999) and the STAAT (1998). The participants of the STAAT meeting concluded that "waste generated by clinical microbiological laboratories constitutes the most dangerous portion of the medical waste stream."

OSHA incorporated the CDC/NIH guidelines in their Proposed Rule on Occupational Exposures to Tuberculosis [Code of Federal Regulations, 1997; paragraph (e)(2)(iv)]. OSHA’s proposal requires that a method of decontamination of waste contaminated with *M. tuberculosis* be available in or as near as feasible to the work area. NIOSH has stated their support for this provision since it will minimize exposures of medical waste treatment workers to viable *M. tuberculosis* (NIOSH, 1998b and 1998c).
Bloodborne Pathogens

Immediately following an exposure to blood or body fluids, or to objects potentially contaminated with blood or body fluids, areas of skin exposed to needlesticks and cuts should be washed with soap and water and then flushed with water. If the incident involves splashes to the nose, mouth, or skin, the area should be flushed with water, while splashes to the eyes should be irrigated with clean water, saline, or sterile irritants. 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. The company should have a program in place that emphasizes and ensures that this reporting and medical follow-up is taking place (CDC, 1988 and 1998b).

In accordance with CDC recommendations for health care workers, all employees should be vaccinated with the HBV vaccine (Kopfer and McGovern, 1993). One to two months after completion of the three-dose vaccination series, employees should be tested for antibody to hepatitis B surface antigen (anti-HBs). 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.

Tuberculosis

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 of M. tuberculosis infection. However, since the DOH investigation indicated occupational tuberculosis transmission at the facility and because workers were potentially exposed to medical waste that may have been contaminated with M. tuberculosis, we recommended that employees continue to be monitored for such infections.

The tuberculosis screening programs should follow the 1994 CDC Guidelines 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 program development, and it should be offered at no cost to employees.

Individual TST results and clinical evaluations should be maintained in a confidential data base. Test results should be reported to individual employees and, when positive, to public health authorities. Summary data (e.g., the percentage of positive reactions among all tested) without identifying information can be reported to management and all employees.

The rate of skin test conversions should be calculated periodically to estimate the risk of acquiring new infection, evaluate the effectiveness of control measures, and to determine the frequency of re-testing.

A tuberculosis education program, prepared in consultation with qualified medical and public health personnel, should be maintained. The training should include the following basic topics relative to tuberculosis: transmission, pathogenesis, diagnosis, symptoms, proper precautions for minimizing risk of infection and active disease, purpose of skin testing, interpretation of TST results, principles of drug therapy, and follow-up procedures for individuals who demonstrate TST conversions. Additionally, periodic updates should be provided to disseminate new information about tuberculosis and to share summary information about the extent of M. tuberculosis infection among employees.

Employee Access to the Containment Room

An appropriately designed change room consistent with current standards and guidelines for biohazard containment facilities (CDC/NIH, 1999) should be made available to employees. The best way to set up clean and dirty change rooms with respect to a zone of contamination is to have one-way flow of employees and supplies (see Figure 2). An airlock should have adequate space if used for gowns and ungowning, along with space for storage and disposal of gowns, masks, and gloves. Hand washing and eye washing facilities must be provided and shower facilities should be considered, depending on the nature of the hazard.

With this type of design, employees would enter the change room through self-closing doors from a corridor (section B) and pass into a clean room (section A). Unused 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 hand wash stations, as well as areas for employees to disinfect their boots and 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 cross-contamination of areas and materials.

Personal Protective Equipment (PPE)

All employees should continue to wear appropriate respiratory protection while working on the plant floor, except after the plant has gone through the general housekeeping and fogging procedures for decontamination, and when the plant is not operating. After the pit has been fogged, employees should be required, at a minimum, to wear a full-facepiece HEPA-filtered negative pressure respirator while in the pit. Since condensation may compromise the worker protection fit factor (Johnson, et al, 1997), methods to minimize its accumulation inside the respirators and more frequent respirator changes should be encouraged among employees. 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 an entire airline 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, NIOSH recommended 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.

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 exit-
ing the containment room. Employees should also be instructed on proper spill response methods including who to contact, what PPE to wear, and how to decontaminate the area.

Employees should receive additional training regarding the use, care, and storage of respirators. The facility should ensure the integrity of respirators being worn by employees (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).

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 frequent basis to prevent potential fire hazards.

Work Practices

Since validation studies for the ETD™ 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. The company should consider automating the process of measuring and recording the temperatures within the vessels which would automatically designate which vessels need to be re-cooked.

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

The company should develop a written protocol outlining the steps to be taken and the types of PPE to be worn in the event of a shut down of the ETD™ waste treatment process.

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.

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 were to become clogged. 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 waste containers 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.

Maintenance

HEPA filters should be leak-tested on a semi-annual basis or when changed. Filters should never be removed from the process flow when in use, 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.

CONCLUSIONS

While the DOH investigation determined that infection with M. tuberculosis in at least one of the facility’s 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 tuberculosis 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 at the facility that could result in employee exposures to aerosolized microorganisms (including M. tuberculosis) and bloodborne pathogens, including:

- the use of a process that creates the potential for aerosolization of possible pathogens contained in the waste due to its being shredded and compacted prior to inactivation;
• deficiencies in the design of the ETD™ process which result 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. In addition, employees may come into direct contact with the waste, including needles and other sharps when clogs occur;

• 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 potential exposures occur;

• the lack of a preventive maintenance program to ensure that the equipment is operating properly, including leak testing of the HEPA filters used in the processing line;

• misconceptions among employees about operations, PPE, and policies and procedures due to an inadequate training program which was not site specific to the work practices performed by employees.

Based on the fact that (1) M. tuberculosis 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 facility processes infectious waste (including cultures of viable M. tuberculosis) which are not inactivated until the waste has been shredded and compacted, and (3) that the ETD™ process creates the potential for aerosolization of the products contained in the waste (including M. tuberculosis), NIOSH concludes that employees could be exposed to potential pathogens (including M. tuberculosis) present in the medical waste.

REFERENCES


