Sterile Technology Industries, Inc., (STI) is a wholly owned subsidiary of Waste Reduction by Waste Reduction, Inc., (WR^2). Our corporate commitment is to protect human and animal health and safety, and the environment, by developing and producing the world's best non-incineration systems for safe, efficient elimination of biological, bio-hazardous, and hazardous waste materials.

Introduction

This document will provide data on actual field testing of STI operating systems processing regulated medical waste resulting from third party investigations for the generation of bio-aerosols and air borne pathogen emissions. First, a brief process description of STI's basic process design and treatment approach is included to obtain a general familiarity with the process. Then, a discussion of Infection Control Background and Practices will follow to establish a clear understanding of what the healthcare industry, professional organizations, and government agencies recommend for designs and methods to reduce or eliminate the risk of airborne infections. The importance of this section is to illustrate the absence of any quantitative exposure standards and measurement standards on these concerns as STI proceeds to discuss its engineering controls and design features derived from guidelines in the healthcare industry. Comparisons with other industry workplaces and ambient air data from various locations are also presented and discussed to illustrate the sound performance and safety of the STI system.

Process Description

The STI Medical Waste Treatment System combines moist steam heat and shredding to produce a solid residue material that is reduced in volume by over 85% and suitable for disposal as ordinary municipal solid waste. Essentially, waste is shredded in a controlled environment and heated with steam ≥ 205 ^{0}F (96 ^{0}C) for a minimum of 60 minutes. The STI system incorporates design features and engineering controls to ensure that there are no harmful emissions or public health risks resulting from the use of the equipment.

Infection Control Background and Practices

The foundation of all infection control programs is identification, isolation, and treatment. STI addresses the prevention of airborne infections, safe workplace conditions and patient environmental conditions through air handling engineering controls and practices involving these major actions:

- Local exhaust ventilation may be used to remove airborne contaminants at or near their source without filtration , if discharged outdoors
- General ventilation may be used to dilute and remove contaminants generated in the space, measured in air changes per hour (ACH);
- HEPA filtration of potentially contaminated air is required if room air is returned to the building ventilation system.

The Environment of Care (EC) chapter of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) hospital accreditation manual contains standards on design and construction of health care facilities. These standards require that organizations utilize the 2001 edition of Guidelines for Design and Construction of Hospitals and Health Care Facilities, published by the American Institute of Architects (AIA) or equivalent construction standards.

The AIA Guidelines provide clear guidance including ventilation, air filter efficiencies, area temperature and humidity, space pressurization and allowance of air recirculation. In addition to the AIA Guidelines, JCAHO requires adherence to applicable National Fire Protection Association (NFPA) codes, American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE), and Centers for Disease Control and Prevention (CDC).

STI based its design philosophy using these guidelines and on technical aspects of recognized infection control programs for facilities that were generating and handling infectious agents.

AIA Guidelines identify the degree to which these practices should be used for specific areas of the hospital. In response to the increasing numbers of immuno-compromised patients, the 2001 revision of the Guidelines contain the most stringent ventilation requirements published to date, including:

- General patient rooms (increase from 2 ACH to 6 ACH)
- Orthopedic operating rooms to use 40 air changes per hour (ach) with 99.97% at 0.3-micron final filter (Cardiology OR at 25 ach with 99.97% filter and general OR at 20 ACH with 90% dust spot filter);
- Operating rooms are required to maintain positive pressure 24/7 to prevent infiltration of contaminants (no shutdown of supply air during off hours);
- Emergency department and radiology waiting areas require negative pressure with 12 ACH and 90% dust spot filter;
- Airborne infectious isolation room(s) in emergency departments and on patient floors are to use 12 ACH, 90% dust spot filter for supply air, 99.97% at 0.3 micron final filter for return air, 125 cubic feet per minute (CFM) offset (exhaust air quantity is greater then supply), 0.01 in. w.g. pressure differential (negative room pressure); and

- Protective environment (PE) rooms for severely immuno-compromised patients require 99.97% at 0.3 micron final filter for supply air, 125 CFM offset (supply greater then exhaust), and 0.01-inch in. water gauge.

At the end of this document please see a table that was taken from the CDC publication *"Guidelines for Environmental Infection Control in Health-Care Facilities"*; *Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) U.S. Department of Health and Human Services; Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333; Dated: 2003*

The design of the STI system has employed techniques and engineering considerations from long established practices and guidelines used in the healthcare industry. Researching federal and industry publications regarding control standards or measurement of air-borne pathogens for worker exposure and health risk concerns found no precise quantitative microbiological standards. *Minimum exposure levels for air-borne bacteria, fungi, and other potentially infectious organisms in the workplace do not exist.*

"Dose–response relationships have often not been described and knowledge about threshold values is (with the exception of a few agents) not available. This relative lack of knowledge is mainly due to the lack of valid quantitative exposure assessment methods." *- Bioaerosol Health Effects and Exposure Assessment: Progress and Prospects; Ann. occup. Hyg., Vol. 47, No. 3, pp. 187–200, 2003*
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In summary, the scientific community, industry professionals, and government health agencies recommend practical air handling and/or ventilation strategies to protect workers and patients from environmental exposure to airborne pathogens.

STI Design Considerations

The STI design strategy for creating a safe working environment incorporates several engineering controls and design features that reduce the risk of potential airborne pathogen emissions:

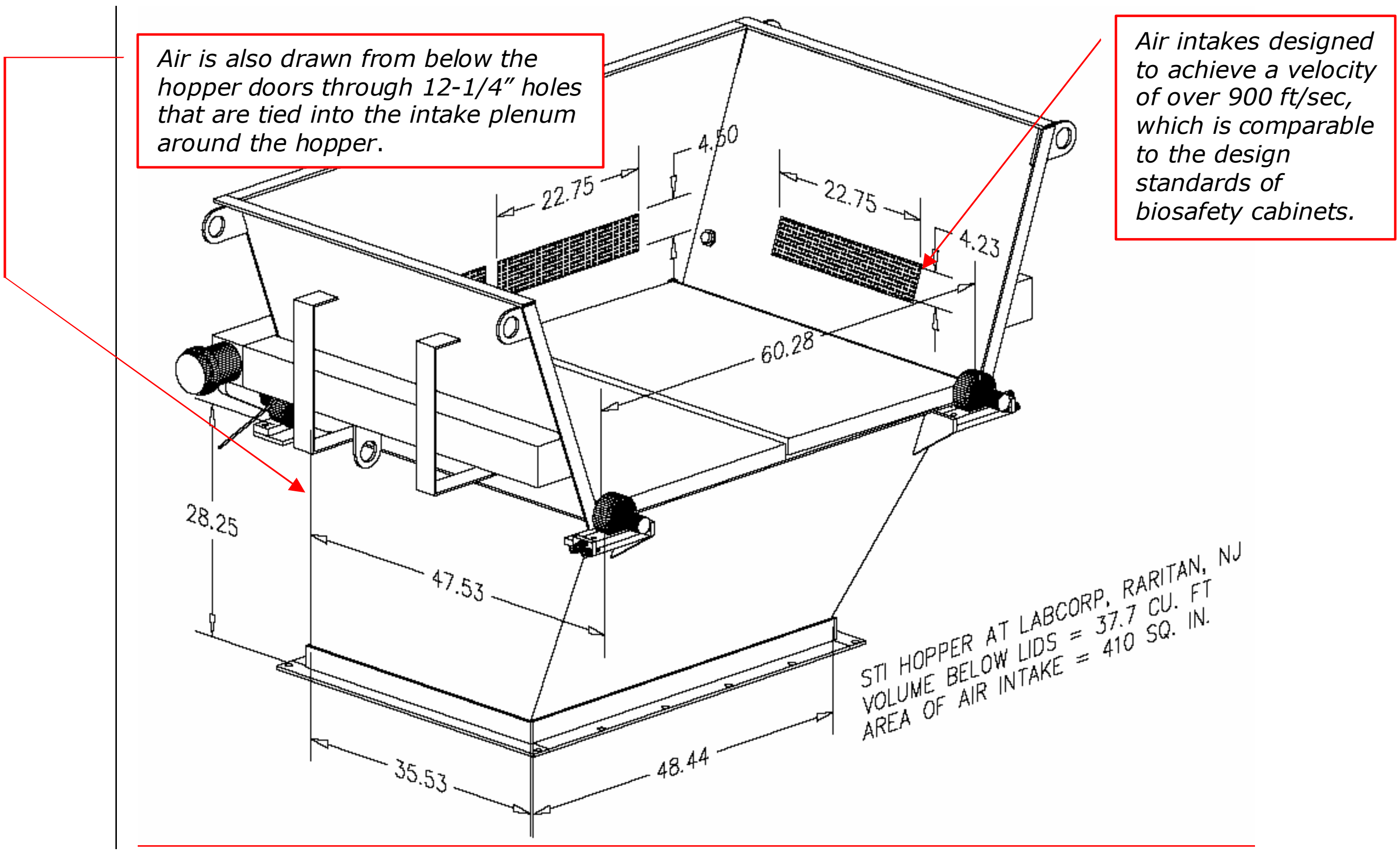
- Users are not required to manually touch the waste for feeding operations, thus minimizing the potential for exposure manipulation nor do they agitate the waste, which might contribute to the creation of bio-aerosols.
- By design, emptying of waste into the in-feed waste hopper and shredding operations occur in a hot moist environment. This process heats these items, greatly reducing the potential for biological growth and contamination from bio-aerosols.

- The hopper doors are opened when the lift bucket reaches the top of the lift and remains open until the lift is completely tilted, plus an additional ten seconds. This overall time amounts to approximately 40 seconds every 5 minutes.
- The shredder operation is a high torque and very low speed (RPM) device that, unlike high speed hammer mill devices, does not vigorously agitate the waste. The shredder is turned on shortly before dumping the waste from the lift into the shredder to ensure that the waste does not bridge above the shredding mechanism.
- Bio-aerosols are created by high velocity agitation or mechanical action such as high speed shredding or human coughing or sneezing. Understanding the mechanics of respiratory infections, as defined by the CDC, the STI system avoids any high velocity mechanical operations in contact with the waste that could possibly aerosolize suspected pathogens. This design consideration uses CDC's guidance on infection transmission as illustrated below:

> *"Respiratory infections can be acquired from exposure to pathogens contained either in droplets or droplet nuclei. Exposure to microorganisms in droplets (e.g., through aerosolized oral and nasal secretions from infected patients) constitutes a form of direct contact transmission. When droplets are produced during a sneeze or cough, a cloud of infectious particles >5 µm in size is expelled, resulting in the potential exposure of susceptible persons within 3 feet of the source person. The spread of airborne infectious diseases via droplet nuclei is a form of indirect transmission. Droplet nuclei are the residuals of droplets that, when suspended in air, subsequently dry and produce particles ranging in size from 1–5 µm. These particles can a) contain potentially viable microorganisms, b) be protected by a coat of dry secretions, c) remain suspended indefinitely in air, and d) be transported over long distances. The microorganisms in droplet nuclei persist in favorable conditions* ***(e.g., a dry, cool atmosphere*** *with little or no direct exposure to sunlight or other sources of radiation)."* - ***Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) U.S. Department of Health and Human Services; Centers for Disease Control and Prevention (CDC) Atlanta, GA 30333; Dated: 2003***

- Steam is injected to scald the shredder and inside the hopper as it rises into both the shredder chamber, the waste and the in-feed hopper by design. This steam has a velocity which is potentially greater than the intake velocity of the filtered air intake vents located within the hopper (see diagram).This maintains a hot, moist environment in both the shredder and the hopper to prevent the spread and growth of pathogens.

- The STI system draws air for around and within the in-feed waste hopper through a HEPA filtration system, and discharges the exhaust to the outside air. The exhaust system is sized for an air flow that would *exceed 10 air changes per minute* based on the volume of the in-feed waste hopper and operates continuously.
- For example, the STI 1000 pph (454 kph) unit is fitted with vent connections on the hopper which are 4" inside diameter (ID) piping connected to a 3-sided plenum intake immediately above the hopper doors. The plenum intake allows for the removal of around 1000 CFM of air from the hopper area and from the ambient environment of the room where the unit is installed.



Due to the perceived sensitive nature of a medical waste treatment installation and the perception of risk, STI has also incorporated a HEPA filter exhaust system that filters the air prior to release of filtered air from the in-feed waste hopper section of the system. The STI system design achieves a continuous exhaust from the in-feed waste hopper area of a *minimum of 10 air changes per minute*. This exhaust passes through a HEPA filter system with an efficiency of 99.97% removal @ 0.3 microns particle. This filter performance specification equals the CDC and AIA guidelines for M. tb. isolation rooms, where unlike the STI system, contaminated air is filtered and returned to the building ventilation system.

STI does NOT re-circulate the filtered air, but rather exhausts this air outside. The STI filtered air system is operational at all times the system is on.

In essence, the STI air handling design basis employs a ventilation rate which is nearly15 times greater than the CDC and AIA recommendations for the most sensitive hospital, or orthopedic operating room conditions. The hopper doors are opened when the lift bucket reaches the top of the lift and remains open until the lift is completely tilted, plus an additional ten seconds. This overall time amounts to approximately 40 seconds every 5 minutes. Further, the HEPA exhaust is discharged to the outdoors (unfiltered air exhaust to the outdoors is the recommended practice by CDC and AIA).

The only other exhaust point from the STI system occurs at the end of the treatment chamber where there is an induced draft vent for the release of steam condensate. The air from this area has been exposed to the same treatment conditions as the waste and does not present a concern of a release of airborne pathogens.

Thus, by design, the STI system prevents the release of untreated and un-filtered bio-aerosols as discussed above, by incorporating engineering controls and practices well beyond the standards recommended by the CDC, AIA and other scientific organizations.

STI Bioaerosol Field Studies

Independent bio-aerosol studies were performed on STI systems and have confirmed the integrity of the STI design. Tests were performed at a 96 TPD commercial medical waste treatment facility using STI technology. That commercial plant also uses the Series 2000, 1000 lb/hr system. Other independent tests were performed in New Jersey on our STI Series 2000, 300 lb/hr (136 kg/hr) processing waste onsite at a healthcare facility. The complete studies are attached to this assessment for review. In summary, the actual data demonstrated that the STI system did not emit bio-aerosols resulting in an unsafe worker environment.

Presented below is a table of air sampling results from the study conducted on the 96 TPD Commercial Medical Waste Processing facility with STI technology. Three samples (H1, H2 & H3) were taken at the exhaust of the HEPA filter system at different times on the same day. The sample B1 was taken as a background sample on the roof of the facility and upwind of the HEPA exhaust vent.

STI Air Sample Results						
96 TPD Commercial Medical Waste Processing Facility in Morgantown, PA						
Sample	*Bacteria*		*Thermophilic Actinomycetes*		*Fungi*	
	(cc)	cfu/m^3	(cc)	cfu/m^3	(cc)	cfu/m^3
H1	5	63	0	<1	3	13
H2	8	100	0	<1	5	63
H3	2	25	0	<1	10	125
B1	30	375	0	<1	11	138
H1, H2 & H3 samples locations at the HEPA exhaust discharge. B1 sample location at the roof upwind of the HEPA exhaust vent.						

The above results reveal that the <u>STI system exhaust showed organism counts less than background readings, demonstrating that the STI system does not create bio-aerosol concerns.</u>

The following table shows air and wipes sampling results at a Hospital Facility in Plainfield, NJ using the STI technology.

STI Air & Wipe Sampling Test Results		
300 lb/hr (136 kg/hr) – STI System at a Hospital in Plainfield, NJ		
Sample No. / Location	*Test Results (colony forming units per m^3)*	
	Viable Fungi	*Viable Bacteria*
#1 Outside – Ambient hospital air Reference Sample	140	<11
#2 Ambient hospital Air Sample by STI Unit	245	82
#2 Wipe Sample at the STI Exhaust Vent Above the Roof	0 (not detected)	0 (not detected)
#3 Ambient hospital Indoor Air Sample in the Waste Receiving Area	94	12

These results verify that the <u>concentration of detectable organisms are insignificant and pose no extraordinary health threat to workers or harm to the surrounding environment.</u>

<u>STI Field Air Testing Results Compared with Non-Medical Waste Environments</u>

As mentioned earlier, <u>there are no published standards quantifying exposure limits for bio-aerosols.</u> However, data exist from studies of other workplace environments and various ambient air locations. It is important to review the <u>STI air sampling data in comparison to these other sources</u> in order to <u>illustrate the high quality performance of the STI design</u> in preventing bio-aerosol concerns.

Following are tables of airborne sampling data from agricultural workplaces and various ambient air locations for comparison with STI data:

Table 5. Airborne bacteria and fungi cfu/m^3 and endotoxin (ng/m^3) in various workplaces - agriculture (from Crook, 1995, Eduard, 1997 and Crook and Swan, 2001)

Work activity	Bacteria	Fungi	Endotoxin (where measured)	Predominant organisms
Grain stores on farms	10^5	10^4	10^3	Fungi including *Aspergillus*
Handling mouldy hay, grain on farms	10^8	10^8		*Aspergillus fumigatus*, actinomycetes
Grain harvesting	10^7 - 10^8	10^5 - 10^7		Fungi including *Aspergillus*, Gram positive bacteria
Animal feed mills	-	10^3	10^1 -10^2	Fungi including *Aspergillus*
Cattle sheds	10^3 - 10^5	10^4 - 10^5	10^3 - 10^4	Fungi including *Aspergillus*
Horse stables	10^5	10^3 - 10^4	10^1 - 10^3	Fungi including *Aspergillus*
Pig houses	10^4 - 10^6	10^4 - 10^5	10^2 -10^4	Gram positive and negative bacteria
Poultry houses	10^5	10^3	10^2	Fungi including *Aspergillus*
Handling mushroom compost	10^7	10^5		Actinomycetes
Picking mushrooms	10^3	10^5		Fungi (*Trichoderma*)
Wood bark composting	10^4 - 10^5	10^6 - 10^7		Fungi (*Paecilomyces*)
STI Unit	***13 – 245***	***25 - 100***		Cladoporium sp., Penicillum sp., Yeast sp., Bacillus sp., Staphylococcus, Rhizopus sp, Aspergillus

Table Source - Occupational and environmental exposure to bioaerosols from composts and potential health effects - A critical review of published data; J. R. M. Swan, A. Kelsey and B. Crook; Health and Safety Laboratory, Sheffield, UK; E. J. Gilbert, The Composting Association, Northamptonshire, UK; Dated: 2003

Table 4. Fungal and bacterial concentrations in ambient air

Location	Airborne fungi (cfu/m^3)	Airborne bacteria (cfu/m^3)	Reference
UK suburban	273 (0-7200)	79 (42-1600)	Jones & Cookson, 1983
UK urban/industrial	1,200	500	Crook & Lacey, 1988
UK in homes	1096 (28-35,000)		Hunter & Lea, 1994
Outdoor ambient, Paris	92 (3-675)		Mouilleseaux *et al* 1994
France	2,999- 9841 max.		Chaumont *et al*, 1990
Netherlands	941		Verhoeff *et al*, 1992
Netheralnds	0 - 15,643		Beaumont *et al*, 1985
Austria rural	185	327	Kock *et al* 1998
Scandinavia rural		99 (2 - 3,400)	Bovallius *et al* 1978
Scandinavia urban		850 (100 - 4,000)	Bovallius *et al* 1978
Finland	750		Nevalainen *et al*, 1994
US urban	930 (0 - >8,200)		Shelton *et al*, 2002
US rural	600	2,000	Folmsbee & Strevett, 1999
US urban	700	1,500	Folmsbee & Strevett, 1999
US rural	8,651 (80-94,000)	3,204 (160-17,600)	Hryhorczuk *et al*, 1996
STI Unit	***13 – 245***	***25 - 100***	Microbiological Chemical Associates, Inc. 1997; S&S Environmental Serivces, Inc. 2002

Table Source - Occupational and environmental exposure to bio-aerosols from composts and potential health effects - A critical review of published data; J. R. M. Swan, A. Kelsey and B. Crook; Health and Safety Laboratory, Sheffield, UK; E. J. Gilbert, The Composting Association, Northamptonshire, UK; Dated: 2003

Conclusion

This presentation of information on the design and performance of **the STI system illustrates the achievement of superior health and safety conditions for the workplace environment.** The STI design considerations use criteria and parameters that **exceed CDC and AIA recommendations.** Furthermore, the actual test results show that the working environment around **the STI system is equal to or better than the conditions in other industries.**

4. Ventilation Specifications for Health-Care Facilities

The following tables from the AIA *Guidelines for Design and Construction of Hospitals and Health-Care Facilities, 2001* are reprinted with permission of the American Institute of Architects and the publisher (The Facilities Guidelines Institute).[120]

Table B.2. Ventilation requirements for areas affecting patient care in hospitals and outpatient facilities[1]

Notes: This table is Table 7.2 in the AIA guidelines, 2001 edition. Superscripts used in this table refer to notes following the table.

Area designation	Air movement relationship to adjacent area[2]	Minimum air changes of outdoor air per hour[3]	Minimum total air changes per hour[4,5]	All air exhausted directly to outdoors[6]	Recirculated by means of room units[7]	Relative humidity[8] (%)	Design temperature[9] (degrees F [C])
Surgeru and critical care							
Operating/surgical cystoscopic rooms[10, 11]	Out	3	15	–	No	30–60	68–73 (20–23)[12]
Delivery room[10]	Out	3	15	–	No	30–60	68–73 (20–23)
Recovery room[10]	–	2	6	–	No	30–60	70–75 (21–24)
Critical and intensive care	–	2	6	–	No	30–60	70–75 (21–24)
Newborn intensive care	–	2	6	–	No	30–60	72–78 (22–26)
Treatment room[13]	–	–	6	–	–	–	75 (24)
Trauma room[13]	Out	3	15	–	No	30–60	70–75 (21–24)
Anesthesia gas storage	In	–	8	Yes	–	–	–
Endoscopy	In	2	6	–	No	30–60	68–73 (20–23)
Bronchoscopy[11]	In	2	12	Yes	No	30–60	68–73 (20–23)
ER waiting rooms	In	2	12	Yes[14, 15]	–	–	70–75 (21–24)
Triage	In	2	12	Yes[14]	–	–	70–75 (21–24)
Radiology waiting rooms	In	2	12	Yes[14, 15]	–	–	70–75 (21–24)
Procedure room	Out	3	15	–	No	30–60	70–75 (21–24)
Nursing							
Patient room	–	2	6[16]	–	–	–	70–75 (21–24)
Toilet room	In	–	10	Yes	–	–	–
Newborn nursery suite	–	2	6	–	No	30–60	72–78 (22–26)
Protective environment room[11, 17]	Out	2	12	–	No	–	75 (24)
Airborne infection isolation room[17, 18]	In	2	12	Yes[15]	No	–	75 (24)
Isolation alcove or anteroom[17, 18]	In/Out	–	10	Yes	No	–	–
Labor/delivery/recovery	–	2	6[16]	–	–	–	70–75 (21–24)
Labor/delivery/recovery/postpartum	–	2	6[16]	–	–	–	70–75 (21–24)
Service							
Food preparation center[20]	–	–	10	–	No	–	–
Ware washing	In	–	10	Yes	No	–	–
Dietary day storage	In	–	2	–	–	–	–
Laundry, general	–	–	10	Yes	–	–	–
Soiled linen (sorting and storage)	In	–	10	Yes	No	–	–
Clean linen storage	Out	–	2	–	–	–	–
Soiled linen and trash chute room	In	–	10	Yes	No	–	–
Bedpan room	In	–	10	Yes	–	–	–
Bathroom	In	–	10	–	–	–	75 (24)
Janitor's closet	In	–	10	Yes	No	–	–