JOURNAL OF THE AMERICAN BIOLOGICAL SAFETY ASSOCIATION

Volume 5, Number 2, 2000
Each Reference Document Includes

Description of Science and Procedures
Chemical, Physical, Biological Agents Used
Regulatory Review (OSHA, EPA, NRC, CDC)
Potential Hazards
Solutions and Control Methods
Safety Checklist (simple and easy to use)
PowerPoint Slides for Training Workers

Call today or visit our website
www.eheinc.com
FREE SAMPLE ($89.95 Value)

Research Laboratory and Biotechnology: Safety Survival Manual

Gel Electrophoresis  PCR  Cell and Tissue Culture
Ergonomics  Autoclaves  Ultracentrifuges

Many More EH&S Topics Covered...

Molecular biology techniques have produced many exciting discoveries. Techniques and procedures that did not even exist 10 years ago are commonplace today. Many laboratory and biotechnology production techniques use hazardous chemicals, radioactive materials and/or biological agents. Some of the chemicals, e.g., ethidium bromide, are mutagens; others, such as acrylamide, are carcinogens. Hydroxylamine can explode if heated inappropriately.

Reflecting the complexity of the science, the environmental health and safety aspects of the molecular biology lab are similarly complex. In addition to chemicals, radioactive materials, laboratory animals and cultured cells/tissues are often needed. From our experiences with clients in these businesses, we found a lack of EH&S resources that explain the science, the need for the agents used, and control methods for performing the work safely and in compliance with current regulations. If you had extra time you could collect the background materials, make telephone calls, check on regulations, write up your findings then prepare a PowerPoint presentation to train the lab workers.

We have done all this for you. We assembled the best information available on the complex techniques and procedures. We focused on making the documents useful to a broad audience by explaining the science behind the techniques and why they are used (for the non-molecular biologist) and thorough coverage of the environmental health and safety concerns (for the non-EH&S professional). These reference documents/tools will help organizations effectively protect the workers and the laboratory or production facility without interfering with the experiment or manufacturing process. The chemicals or operations covered are common to organizations from university laboratories to biotechnology production facilities. The Research Laboratory and Biotechnology Safety Survival Manual comes with 10 guidance documents with an additional document each month for 12 months for a total of 22 Guidance Documents.
VOLUME 5

NUMBER 2, 2000

JOURNAL OF THE AMERICAN BIOLOGICAL SAFETY ASSOCIATION

ABSA'S VISION, MISSION STATEMENT, AND GOALS.........................................................39

PRESIDENT'S PAGE..........................................................................................................40

GUEST EDITOR'S PAGE......................................................................................................41

ARTICLES

Infectious Waste Disposal in Developing Countries: Recommended Minimal Practices from a Hospital Survey in Southeast Asia — Eugene C. Cole........................................42

Missing the Point: A Review of Needlestick Injury and Occupational Risks from Bloodborne Viruses — David R. Morgan.................................................................47

Medical and Infectious Waste Management — Ira F. Salkin, Edward Krisiunas, and Wayne L. Tumberg ........................................................................................................54

A Tuberculosis Outbreak Among Medical Waste Workers — Angela M. Weber, Yvonne Boudreau, and Vincent D. Mortimer ..........................................................70

VIEWPOINT

Arthropod Containment Guidelines Under Development — Mark Q. Benedict........89

ANNUAL INDEX..................................................................................................................93

GUIDELINES FOR SUBMISSIONS..................................................................................95
Journal of the American Biological Safety Association (ISSN 1091-3505) is published quarterly by the American Biological Safety Association (ABSA). ABSA members receive the journal as a benefit of membership. An additional annual subscription for members is $60. Nonmembers and institutions/libraries may subscribe at the annual rates of $92 and $122 respectively. Single issue rates are as follows: members $18; nonmembers $28; and institutions/libraries $35.

Authorization to Copy: No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, electrostatic, magnetic tape, photocopying, recording, or otherwise, without permission in writing from the copyright holder.

Change of Address: A change of address notice should be sent at least six weeks in advance to the ABSA National Office to ensure that all mailings, including the journal and newsletter, will reach you. ABSA is not responsible for misrouted mail as a result of insufficient notification of an address change. Undelivered copies resulting from an insufficient address change notification will not be replaced, but issues may be purchased at the single issue price as detailed above.

ABSA NATIONAL OFFICE
American Biological Safety Association
1202 Allanson Road
Mundelein, IL 60060-3808, U.S.A.
847-949-1517 / Fax: 847-566-4580
E-mail: estygariii@aol.com
Web Site: www.absa.org

<table>
<thead>
<tr>
<th>ADVERTISING RATES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RATES</strong></td>
</tr>
<tr>
<td>Outside back cover</td>
</tr>
<tr>
<td>Inside front cover</td>
</tr>
<tr>
<td>Inside back cover</td>
</tr>
<tr>
<td>Full page</td>
</tr>
<tr>
<td>1/2 page</td>
</tr>
<tr>
<td>1/4 page</td>
</tr>
</tbody>
</table>

Color rates: $250 for first color (after black) and $200 each additional color. 15% discount for agencies (orders must be supplied on agency letterhead).

<table>
<thead>
<tr>
<th>MECHANICAL REQUIREMENTS</th>
<th><strong>Width</strong></th>
<th><strong>Height</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outside back cover (full bleed)</td>
<td>8-1/2”</td>
<td>11”</td>
</tr>
<tr>
<td>Inside front cover (full bleed)</td>
<td>8-1/2”</td>
<td>11”</td>
</tr>
<tr>
<td>Inside back cover (full bleed)</td>
<td>8-1/2”</td>
<td>11”</td>
</tr>
<tr>
<td>Full page</td>
<td>7”</td>
<td>10”</td>
</tr>
<tr>
<td>1/2 page - horizontal</td>
<td>7”</td>
<td>4-7/8”</td>
</tr>
<tr>
<td>1/2 page - vertical</td>
<td>3-3/8”</td>
<td>10”</td>
</tr>
<tr>
<td>1/4 page</td>
<td>3-7/8”</td>
<td>4-7/8”</td>
</tr>
</tbody>
</table>

8-1/2” x 11” trim size
133 line screen, right reading, emulsion side down

SUBMISSION DEADLINES
January 4 for Winter issue—April 4 for Spring issue
July 4 for Summer issue—October 4 for Fall issue

The publication of any advertisement by this journal is not an endorsement of the advertiser or of the products or services advertised. ABSA is not responsible for any claims made in any advertisement.

JOURNAL

Editor
Richard C. Knudsen

Associate Editor
Ira F. Salkin

Overseas Editor
Barbara Johnson

Production Editor
Karen D. Savage

Publications Committee Chair
Joseph Van Houten

Publications Committee
Phil Hagan
Jonathan Y. Richmond
Cecil Smith

ASSOCIATION OFFICERS

President
John H. Keene
Biohaztec Associates, Midlothian, VA

President-Elect
Debra L. Hunt
Duke University Medical Center, Durham, NC

Secretary
Richard Rebar
SmithKline Beecham Pharmaceutical
King of Prussia, PA

Treasurer
Art Rutledge
Saf-T-Pak, Inc., Edmonton, Alberta, Canada

Past President
Marilyn Misenhimer
University of Southern California, Los Angeles, CA

Council Members
Maureen Best, Councilor
Tunney’s Pasture, Ottawa, Ontario, Canada
Karen Byers, Councilor
Dana Farber Cancer Institute, Boston, MA
Richard Gilpin, Councilor
Johns Hopkins Institutions, Reisterstown, MD
Elizabeth Gilman, Councilor
Boston University Medical Center, Boston, MA

Executive Director
Edward J. Stygar, Jr.
VISION

ABSA, the leader in the profession of biological safety.

MISSION STATEMENT

The American Biological Safety Association is dedicated to expanding biological safety awareness to prevent adverse occupational and environmental impact from biohazards.

GOALS

• Expand professional and public awareness of biological safety through effective communication.
• Participate in the development of biological safety standards, guidelines, and regulations.
• Develop ABSA as the recognized resource for profession and scientific expertise in biological safety.
• Advance biological safety as a scientific discipline through education, research, and professional development.
• Develop and maintain standards for biological safety professionals.
PRESIDENT’S PAGE

As I complete my year as President of ABSA, I look forward, as should you, to a new and improved means of communication and publication for our membership. Biosafety today encompasses a wide range of topics and concerns. We have come from an organization made up of laboratory scientists interested in lab safety to an organization whose membership now includes those laboratory scientists as well as occupational safety and health professionals from industry, academia and government, and persons interested in legislation of health and safety issues. ABSA is truly an international organization, with our Canadian Affiliate, and our newest Affiliate organization in Brazil, as well as our members from all over the world. We must be receptive to the needs and concerns of all of our members.

This year has marked an era of change for the Journal and the Publications Committee, under the leadership of Chairperson Joe Van Houten, Editor Richard Knudsen, and Associate Editor Ira Salkin, has recommended changes in the journal format that should allow us to provide a more varied content to the membership. The Council has reviewed the recommendations and has approved them with a great deal of enthusiasm. The new format requires that a number of Assistant Editors be drawn from the membership to develop new content material that will be of interest and assistance to the membership. The search for these volunteer editors is underway and should be completed in the very near future. If you are asked to serve and can find the time, it is our hope that you will accept and provide your expertise to the organization and the rest of the membership. The new journal format will help this organization to reach its goal of becoming the preeminent biosafety organization in the world.

The articles in this edition of the journal provide a range of biosafety issues that are of interest, not just to laboratory safety personnel, but to many others of our members. This is in keeping with our goals and objectives and provides a mechanism for reaching out beyond our organization to those to whom we can be of service. As we go forth with the new publication, in the near future, please let the editors and the council know whether or not the new format meets your expectations and is of assistance to you in your practice of the science of biosafety. It is only through your feedback that we can continue to improve our means of communication and education of our members.

As President of ABSA, I would like to congratulate the editors and the Publications Committee members for their hard work and vision in proposing these changes and wish them the best of luck in making the journal the best biosafety publication in the world. Well done!

John H. Keene
Biohaztec Associates
Midlothian, Virginia
GUEST EDITOR'S PAGE


In 1988, the Congress of the United States enacted the Medical Waste Tracking Act in response to public pressure brought about by several incidents purportedly involving regulated medical waste (RMW) washing-up along the coasts of three Northeast states. It was further alleged that this waste had entered New York City harbor as a result of illegal disposal activities of one or more waste haulers. It would later be established that very little of the waste contained what would be defined as RMW components, and that the materials had entered the harbor through the New York City storm drainage system rather than through the unlawful actions of waste transporters. However, these facts did not prevent the legislatures of a majority of states from promulgating their own laws and regulations to control the generation, processing, treatment and disposal of RMW. Although the federal statute “sunset” in 1991, most states and several federal agencies maintain some form of regulatory oversight over the waste generated through the delivery of health care and research involving potential human infectious agents.

While several studies over the last 10 years have demonstrated that there are occupational risks associated with RMW, there has not been, to the guest editor’s knowledge, a single report documenting the acquisition of an infectious disease among the public related to RMW. Most of the investigations which have been published in the literature have found that the general public’s health would not likely be adversely affected by RMW generated by health care facilities.

However, the public perceives RMW as a real and direct health threat. The numerous reports in the popular press of physical injuries (generally needles/sticks) caused by RMW, especially when they occur in such public locations as parks and playgrounds, magnify the threat posed by RMW in the collective mind of the public. In addition, the public’s fears have been further heightened by the perception that RMW is generated by health care facilities treating patients for those exotic, emerging infectious diseases described in Time, Newsweek, and similar publications. Whenever the public’s perception of any issue, in this instance, the health threats posed by RMW, clashes with the results of scientific investigations of the same issue, perception invariably wins.

The myriad of state, federal and even international RMW regulations and the public’s perception of RMW as a threat to its health and safety has resulted in the development of a billion dollar industry in the United States. Manufacturers of autoclaves and alternative treatment technologies, RMW haulers, commercial treatment centers and landfill operators are a few of the components of this rapidly evolving industry. As biosafety professionals, we must be cognizant of the public’s perception of RMW, the claims made by the industry, the regulatory demands of state and federal agencies and be capable of weighing these factors against the reality that RMW is a low risk—high consequence hazard. To assist the Association’s members, I have assembled four articles in this issue which discuss distinctly different aspects of the RMW issue, i.e., the threat posed by accidental needles/sticks, development of effective and low cost RMW treatment procedures for non-industrialized countries, an investigation of a tuberculosis outbreak at a commercial medical waste treatment site and the republication of a chapter from Anthology of Biosafety II: Facility Design Considerations, which describes medical and infectious waste management in industrialized countries. I trust that these reports will allow you to better understand the problems associated with RMW so as to appropriately manage the RMW generated in your institutions.

Ira F. Salkin
New York State Department of Health
Albany, New York
INFECTIOUS WASTE DISPOSAL IN DEVELOPING COUNTRIES: RECOMMENDED MINIMAL PRACTICES FROM A HOSPITAL SURVEY IN SOUTHEAST ASIA

Eugene C. Cole  
DynCorp Health Research Services, Morrisville, North Carolina

ABSTRACT

When managed ineffectively, infectious hospital wastes in developing countries can compromise the quality of patient care and create significant occupational, public, and environmental health risks. Three types of hospital facilities in a developing country were studied to assess waste separation, transport, treatment, and disposal practices. The staff of a municipal General Hospital (1,650 beds) did not appropriately separate wastes and disposed of untreated solid wastes by surface dumping near the hospital grounds, pending municipal collection and disposal in an unsecured landfill. While personnel of a rural Divisional Hospital (150 beds) did not effectively separate sharps from other forms of medical waste, they disposed of all solid wastes on hospital grounds in a secured ground pit, followed by burning and soil cover. Workers at a rural Township Hospital (25 beds) separated wastes and disposed of them by; (i) burning general and most medical wastes in a ground pit, (ii) using a separate pit with metal cover and delivery tube to burn needle and other sharps, and (iii) incinerating all forms of paper wastes.

While no hospital had a written waste management policy or provided waste management training to employees, the smaller, rural hospitals accomplished effective waste disposal using no- to low-cost minimal practices. Furthermore, their procedures prevented scavenging and reduced risks for environmental pollution, as well as the transmission of common and emerging infectious disease agents. In addition to promoting effective minimal treatment and disposal practices, as in ground pits, when no other options are available, recommendations for developing countries include; (i) a written waste management policy, (ii) separation of sharps from other forms of medical waste, (iii) development of a safe storage and transport procedures, and (iv) providing training and protective equipment to those who work directly with hospital waste.

HOSPITAL FIELD SURVEY

In response to a request from a national government in southeast Asia, the World Health Organization (WHO), South-East Asia Regional Office, New Delhi, funded a two week field survey to identify inadequacies of the country’s current systems of infectious and other hazardous hospital waste disposal and provide recommendations for effective no- to low-cost management practices. The survey team first discussed hospital waste management issues with WHO representatives and key national government officials, and then visited three types of hospitals, i.e., a city General Hospital (1,650 beds), a rural Divisional Hospital (150 beds), and a rural Township Hospital (25 beds). Waste practices were observed at each facility with the assistance of its management personnel. All waste procedures from generation through separation, storage, transport, treatment, and disposal were evaluated. Written policies, worker training and protection, as well as the overall waste management needs of each facility were discussed with hospital management.

There were important differences in waste segregation, treatment, and disposal practices among the hospitals inspected. Both the on-site visits and meetings with officials demonstrated that more effective hospital waste management was desired, and that waste management practices could be improved within all types of hospitals.

FINDINGS

General Hospital

The General Hospital (1,650 beds) located in the nation’s capital city, had poor waste separation practices which, when combined with its procedure of surface dumping of all infectious wastes, created significant occupational, public, and environmental health risks. In particular, needles and other sharps were not separated from the waste stream, chemicals were discharged into a drain line on hospital grounds, and transport of wastes throughout the hospital was done manually. Waste
disposal consisted of surface dumping of untreated wastes adjacent to hospital grounds, followed by municipal collection and landfill deposition. This created a substantial public health risk from scavenging, as well as a major occupational health risk for city workers responsible for collecting the loose, scattered, and potentially hazardous wastes.

**Divisional Hospital**

This 150-bed rural hospital used minimal treatment and disposal practices consisting of:

- A secured, fenced area to prevent scavenging; and
- A ground pit for burning all general and infectious wastes (Figure 1).

There was, however, no plan for proper treatment and disposal of infectious wastes during the rainy season when the pits are flooded. As with the General Hospital, chemical wastes were discharged into a surface drain line onto the hospital grounds.

**Township Hospital**

This 25-bed rural hospital utilized an impressive system of minimal treatment and disposal practices consisting of:

- A ground pit for burning all infectious and most general wastes;
- A separate ground pit with metal cover and delivery tube for sharps disposal (Figure 2);
- A small, single-chamber incinerator for paper wastes (Figure 3); and
- A secured, fenced area to prevent scavenging.

As with the 150-bed hospital, this hospital also had problems with its waste treatment and disposal during the rainy season.

**SUMMARY**

None of the hospitals had a written waste management policy or plan, or provided waste management training for employees. In general, some personal protective equipment, such as gloves, were provided to workers who directly handled the wastes, but typically the employees were not immunized with the hepatitis B vaccine. Furthermore, none of the hospitals had a coding system for waste receptacles to permit staff to easily identify and separate hazardous hospital wastes.

The rural hospitals did, however, implement acceptable, low-cost, minimal practices for infectious waste treatment and/or disposal. Administrators were eager to receive guidance on how to more effectively manage hazardous hospital wastes, particularly during the problematic rainy season.

**MINIMAL PRACTICES RECOMMENDATIONS**

1. All hospitals in developing countries should work to minimize waste-related transmission of infectious disease agents through implementation of no- to low-cost minimal effective practices for infectious waste treatment and disposal.
2. All hospitals should have a written policy on the management of infectious wastes and provide training for workers responsible for waste handling.
3. Needles and other sharps must be separated from other types of waste. This would enhance the protection of those who collect, transport, treat, and dispose of wastes. Needles should not be recapped, but deposited directly into dedicated, puncture-proof containers. Used and empty plastic or glass bottles can provide low-cost solutions. A color-coding or similar system to assist workers in separating and identifying wastes is strongly encouraged.
4. The transport of infectious waste containers throughout a hospital should never be done manually, but only by means of covered carts or similar conveyances. This minimizes direct contact with a worker's body and prevents any leaking wastes from spreading contamination.
5. Chemical wastes should not be discharged onto hospital grounds but stored in leak-proof containers that are returned to the supplier for disposal or to a private contractor for reprocessing/recovery or otherwise dealt with as per acceptable disposal practices, in accordance with environmental regulations.
6. Hospitals should strive to ensure that infectious solid wastes receive treatment to reduce the threat to public health and safety. Such wastes should not be permitted to be deposited untreated in a landfill or other surface-dumping site. A steam autoclave, if available, may be used to effectively treat non-chemical types of infectious wastes prior to final disposal. Hospitals should work to procure an autoclave or alternative treatment system.
7. In the absence of infectious waste treatment by steam autoclaving or alternative technology, facilities are encouraged to use single-chamber incinerators, drum incinerators (Figure 4), or pit burning with burial of the resulting ash, as minimal treatment and disposal practices.
8. Wastes awaiting treatment should be stored in
FIGURE 1
Ground pit for burning infectious and general hospital wastes.

FIGURE 2
In-ground sharps disposal system.
FIGURE 3
Single-chamber incinerator.

FIGURE 4
Drum Incinerator.
a secure area to prevent human and animal scavenging. Hospitals using pit deposition and burning should establish these sites on high-ground, and seek other solutions so that effective treatment and disposal can continue during the rainy season.

9. Workers involved directly in handling infectious hospital wastes should be provided with appropriate protective equipment and supplies, such as eye protection, gloves, protective gowns, and hand-washing agents and disinfectants.

10. The central governments are encouraged to develop a national policy for hospital waste management based on the Action Plan for the Development of a National Programme for Sound Management of Hospital Wastes (WHO/SEARO, 1997). They could also require hospitals to establish effective waste management practices, as contained in Suggested Guiding Principles and Practices for the Sound Management of Hazardous Hospital Wastes (WHO/SEARO, 1997). Both documents were developed as a result of a Regional Consultation on Sound Management of Hospital Wastes, held in Chiang Mai, Thailand in 1996.

DISCUSSION

Both the Divisional and Township hospitals had effectively implemented economical, minimal practices necessary to contain, treat, and dispose of hazardous hospital wastes. In so doing, they significantly reduced the risk of transmission of common and emerging infectious disease agents. While neither had a formal waste program, they did implement a number of the most significant management techniques, including waste separation, treatment (burning), disposal (burying), and security (preventing human scavenging). Most importantly, these management principles were being practiced at little or no cost, as their implementation required primarily manpower that was readily available on each hospital’s staff. These minimal practices support the philosophy that it’s better to do “something” to address infectious waste treatment and disposal than “nothing at all”!

It was obvious that the minimal practices in place at both rural hospitals were in large part due to the enthusiasm of the hospital administrators, who were eager to have their waste collection and disposal systems assessed in order to learn how to make additional improvements.

It was discouraging to see the General Hospital separate the infectious from the general wastes, and then transport the infectious wastes outside the hospital to be dumped over the wall. While the dumping area was officially a pickup point for the city refuse collectors, it provided an excellent opportunity for human and animal scavenging and as a result, increased public, occupational, and environmental health risks.

Developing countries worldwide are currently faced with the difficult challenge of containing the spread and resultant economic and social impacts of a variety of common and emerging infectious diseases. While great efforts are needed in the areas of diagnosis, treatment, nutrition, sanitation, and public health education, attempts at reducing the risks for infectious disease transmission must also include effective treatment and disposal of hospital wastes.

CONCLUSION

The results of this field survey have shown that minimal practices can contribute to the reduction of human health risks associated with inappropriate infectious hospital waste management. It is recommended that in the absence of a more sophisticated program of waste treatment and disposal, governments of all developing countries actively promote the minimal practices concept. The results of this study have contributed to the minimal practices concept for infectious and other hazardous healthcare wastes described by the World Health Organization in its recently published text (Pruss et al, 1999).

ACKNOWLEDGEMENT

The author acknowledges A. Pierre Hirano and John C. Pospisil, World Health Organization, South East Asia Region, New Delhi, India, for their valuable guidance regarding the conduct of the survey. This manuscript was presented, in part, at the International Emerging Infectious Diseases Conference in March 1998 in Atlanta, Georgia.

REFERENCES


MISSING THE POINT: A REVIEW OF NEEDLESTICK INJURY AND OCCUPATIONAL RISKS FROM BLOODBORNE VIRUSES

David R. Morgan
British Medical Association, London, United Kingdom

ABSTRACT

Hundreds of thousands of occupational exposures to the blood and body fluids of patients can occur each year in healthcare settings. Accidental needlestick or “sharps” injuries caused by hollow-bore needles, scalpels or other sharp objects constitute an important occupational health hazard for healthcare professionals and provide the most important route of infection of healthcare workers by human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV).

Both anecdotal and survey data suggest that healthcare students and professional staff receive variable and often inadequate education and training in infection control. The purpose of this article is to present an update about occupational infection risks, with details of a new interactive CD-ROM which provides key infection control training materials on bloodborne viruses, for students and staff.

INTRODUCTION

Sharp instruments, particularly disposable hollow-bore hypodermic needles, are used, worldwide on a daily basis throughout healthcare facilities. It has been estimated that about 200 million hypodermic needles were used in the UK alone in 1998 (Ely, 1999). “Sharps” may constitute a low infection risk for the general public when subject to careful storage, transport and destruction. However, for physicians, nurses, laboratory workers, waste handlers and other staff they present a very important risk of infection from bloodborne pathogens, which may greatly outweigh immediate health risks from other constituents of clinical waste. Published reports suggest that healthcare care students, professional staff and ancillary staff receive variable and often inadequate education and training in infection control and the processing of clinical waste.

BLOODBORNE VIRUSES

Although more that 20 pathogenic organisms may be transmitted in blood (Collins and Kennedy, 1987), three bloodborne viruses, Human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV) present particular risks. Each of these viruses can be spread by sexual contact, but blood to blood contact is the most efficient transmission route, and infection can occur following an injury with a contaminated sharp instrument.

Hepatitis B virus has been identified as a potential hazard since 1949, when a blood-bank technician, whose jobs included sharpening needles from reusable transfusion-giving sets, developed acute hepatitis following injury. However, despite the fact that HBV is significantly more infectious than HIV, concern about preventing bloodborne infections did not reawaken until the risk for occupational HIV infection by exposure to blood was identified in the early 1980s. With the availability of an accurate test for HCV, it is now clear that infection with this virus is widespread in certain populations, especially intravenous drug users, and infection may lead to serious long-term illness. The presence of these infections in patients will provide a risk of infection for those undertaking venepuncture, laboratory or invasive clinical techniques, and where percutaneous injury with contaminated sharps or mucous membrane exposure by blood may occur.

Hepatitis B (HBV)

Hepatitis B virus may circulate in the blood of infected patients in titres greater than 10^{13} infectious units per millilitre (CDC, 1985). It can remain viable on hard surfaces within dried blood or in liquid blood in syringes at room temperature for at least seven days, and possibly much longer. Thus, even a tiny amount (0.04 microlitre) of blood or serum may infect a health worker if percutaneously injected, or splashed onto the eyes or mucous membranes. Blood on the hands of healthcare workers may lead to inadvertent exposure through
pre-existing cuts, lesions or broken skin, or be rubbed into the eye subsequent to the exposure (Breuer and Jeffries, 1992). There is no evidence of transmission of HBV by inhalation of droplets or aerosols. The hepatitis B virus is very stable; it is resistant to common antiseptics, such as chlorhexidine and is not destroyed by boiling for less than five minutes. Use of hypochlorite, glutaraldehyde, chlorine and autoclaving at 134°C for a minimum of three minutes are methods/techniques known to destroy the virus.

**Hepatitis C (HCV)**

Hepatitis C virus may be present in body fluids other than blood and has been detected in ascitic fluid, seminal fluid and urine from patients with chronic liver disease who are serum HCV RNA positive. Hepatitis C virus antigens have been demonstrated in liver biopsy sections and HCV-positive hepatocytes were found to be scattered in the lobules. It is likely that the infection can be transmitted via transplanted organs and bone grafts, and HCV is thought to be the chief cause of post blood transfusion hepatitis; up to 90% of blood donors with antibody to HCV have infectious virus particles in their blood (Esteban, 1990).

The amount of circulating HCV RNA in samples studied thus far appears to be lower than for HBV but may be higher than in HIV infected individuals. Kiyosawa, et al. (1991) followed up 110 Japanese healthcare workers after percutaneous exposures to infected patients. Four developed clinical hepatitis and three became anti-HCV positive, representing a transmission rate of 2.7%. In a second study, 5 out of 68 anti-HCV negative healthcare workers who sustained percutaneous exposures to infected blood subsequently developed elevated serum transaminases after exposure. Anti-HCV and HCV RNA were detectable in three subjects and HCV RNA alone was detectable in the other two, for an overall transmission rate reported of 7 of 68 (10%). Decontamination processes used for HBV should also inactivate HCV.

**Human Immunodeficiency Virus (HIV)**

Early on in the HIV/AIDS epidemic occurring in the United States it was felt that HIV did not pose a major risk for occupational infection in healthcare workers. Concern began to be shown in 1984 after the first case of documented sero-conversion following percutaneous exposure to blood was reported. Today, there are few countries that do not report significant prevalence rates for this virus (Table 1). About 16,000 new HIV transmissions occur each day and the virus is spreading most rapidly in developing countries (90% of cases). HIV has been isolated from peripheral blood mononuclear cells in 97% of persons who were HIV antibody-positive, confirming that all HIV-antibody-positive patients are potentially infectious and that cell-free body fluids such as plasma should also be considered to be infectious, whether patients are asymptomatic or symptomatic. Although the plasma HIV titres may be considerably lower than for HBV, small quantities of blood may still be able to effect transmission (Table 2).

The virus has been reported to be inactivated by treating at 56°C for 30 minutes but can survive under laboratory conditions for 7 days at room temperature (20-22°C), either in dry or liquid media and viable virus has been recovered from a cadaver up to 16 days after death. Studies have shown that HIV is inactivated rapidly by commonly-used chemical disinfectants such as sodium hypochlorite solution, at a concentration of 10,000 ppm (1%).

**RISK ASSESSMENT**

Hundreds of thousands of occupational exposures to blood and body fluids of patients occur each year in health care settings and blood has been implicated as the source of the exposure in nearly all occupationally acquired infections. The actual risk to an individual health care worker or waste handler of contracting a blood-borne virus depends on a number of variables, including:

- seroprevalence of the virus in the source (patient) population;
- known or suspected infectious status of the individual patient;
- infectivity of the virus;
- risk category of the clinical procedure;
- degree of exposure to blood at the time of the incident; and
- the provision of post exposure prophylaxis.

Freshly drawn blood, taken from a highly viraeemic HBV infected patient which enters the body of a healthcare worker via a deep needlestick injury, is most likely going to lead to infection (1 in 3 risk). In comparison, HIV transmission following a single sharps injury presents about 1 in 300 risk, derived from a review of 25 follow-up studies carried out worldwide. This contrasts with the results of 21
studies of mucocutaneous HIV exposures, which indicate a risk of 1 in 2,910 per high risk event. Approximate transmission risks for the three agents following needlestick injury can be compared using the “rule of threes” (Table 3).

SURVEILLANCE OF STAFF WITH OCCUPATIONAL EXPOSURE TO BLOODBORNE VIRUSES

It has been estimated that in Europe, up to 6.8 million workers and students are potentially exposed to the hazards of blood contact, although the United States has the largest number of recognised cases of occupationally-acquired HIV infections in the world. By December 1997, 286 staff were reported, worldwide, to have acquired HIV occupationally, an increase of 104 over the three-year period 1994-7. Evans noted in 1999 that the majority of cases (56%) were reported from the US, followed by mainland Europe (33.5%; Table 4).

In the US, estimates indicated that between 252,000-756,000 sharps injuries occurred in 1990.

**TABLE 1**

Estimated worldwide prevalence of HIV and Hepatitis B and C Viruses.

<table>
<thead>
<tr>
<th>Virus World Prevalence</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV: 350 million individuals</td>
</tr>
<tr>
<td>HCV: 500 million individuals</td>
</tr>
<tr>
<td>HIV: 30 million individuals</td>
</tr>
</tbody>
</table>

**TABLE 2**

Approximate number of infectious units of virus per millilitre of patient blood.
(Source: Bennett and Howard, 1994)

<table>
<thead>
<tr>
<th>Virus</th>
<th>Number of particles/ml of infected blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV</td>
<td>$10^6 - 10^{13}$</td>
</tr>
<tr>
<td>HCV</td>
<td>$10^9$</td>
</tr>
<tr>
<td>HIV</td>
<td>$10 - 10^3$</td>
</tr>
</tbody>
</table>

**TABLE 3**

Approximate occupational transmission risks for HBV, HCV, and HIV, following injury with a sharp with infected blood.

<table>
<thead>
<tr>
<th>Virus Transmission Risk (highest)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV:</td>
</tr>
<tr>
<td>HCV:</td>
</tr>
<tr>
<td>HIV:</td>
</tr>
</tbody>
</table>

**TABLE 4**

Worldwide distribution of reported occupationally acquired HIV infection.

<table>
<thead>
<tr>
<th>Region</th>
<th>Occupationally acquired HIV infections</th>
<th>Number of AIDS cases (Alive Dec '97)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Europe</td>
<td>40</td>
<td>417,000</td>
</tr>
<tr>
<td>USA</td>
<td>160</td>
<td>820,000</td>
</tr>
<tr>
<td>Africa</td>
<td>6</td>
<td>21.2 million</td>
</tr>
</tbody>
</table>
Fifteen occupational health departments from Wessex and Oxford regions in the UK found that 1102 incidents were reported over a nine-month period (Smedley, 1995). Such studies however, cannot give an accurate picture of the problem as many incidents go unreported. Jagger and colleagues in the US have reported categories of staff that are at the highest risk of sustaining sharps-injury associated HIV infection. Fifty-eight hospitals in the US provided sharps injury data over one year in which there were a total of nearly 4000 high risk injuries during blood taking. Nurses and phlebotomists ranked first as highest risk, followed by physicians.

A review of all incidents involving blood/body fluid exposure of staff reported to the Royal Free Hospital occupational health unit in London in 1996 also showed that nurses experienced the most reported incidents (41%), followed by physicians (15%). In contrast, porters or housekeeping staff suffered only 1% of reported exposures.

Accidental injuries can occur in various ways to the person using the sharp instrument, but the most significant cause is a result of resheathing contaminated needles. Up to 40% of injuries may be due to this single procedure which is discouraged by many organisations including the British Medical Association (BMA, 1990), US Centers for Disease Control and Prevention and the World Health Organisation.

A BMA postal survey (Morgan, 1997) of nearly 2000 UK medical students in 1992 revealed that many were at risk of infection due to unsafe practices, with high rates of resheathing reported and 25% recalling one or more injuries over the previous year. Only 42% of students (816/1950) stated that they would definitely report a future needlestick injury.

A review of recently published literature confirms that reporting rates of needlestick injuries are still low (Luthi, 1998; Hettiaratch, 1998; Haiduven, 1999). The reasons given by staff include little or no perception of risk, being too busy, and dissatisfaction with follow-up procedure. Surgeons may underestimate the risk of bloodborne pathogens and as a result use gloves selectively and/or not use double gloving techniques, even though gloves may provide significant benefits by reducing the volume of blood transferred during a sharps injury (Mast, 1993; Bennett, 1994).

HEALTH AND SAFETY LEGISLATION

In the UK, the emotional and financial costs of sharps injuries to the National Health Service are significant. In October 1998, UK newspapers reported an out-of-court settlement for £465,000 (approximately $765,000 US) damages between a junior hospital doctor and the employing health authority. The doctor had developed a "needle phobia" following an accidental injury and was unable to continue practising medicine. She had been qualified for less than a year when she pricked herself on a needle left on a drugs trolley at a London hospital. The doctor struggled to cope with her growing anxieties about sharps, blood and AIDS for two years before going on sick leave in 1994; she is unlikely to work again as a physician.

The BMA has emphasised the responsibility of employers for providing full sharps training and hepatitis B vaccine for all those at the "sharp end," with post-exposure counselling, assessment and occupational support. Post exposure treatment using AZT in combination with other drugs should be considered for staff following a high risk HIV exposure. It is likely that many health authorities and trust hospitals have yet to get the situation fully under control.

The UK Department of Health has confirmed that all employers have a legal obligation "to ensure that their employees are appropriately trained and proficient in the procedures necessary for working safely." In the US, needlestick injuries have long provided the basis for litigation in a variety of settings and the award of nearly half a million pounds to one UK physician is likely to be just the tip of the financial iceberg. New laws requiring syringes to be fitted with retractable needles or plastic sheaths, which are now required in California, have not yet been proposed for the UK.

INFECTION CONTROL MANAGEMENT AND TRAINING

Health authorities have been reminded by the UK Departments of Health (DOH, 1998) of their responsibility to draw up local guidelines and to establish an infection control team to liaise with the occupational health service, which should advise managers and employees on all aspects of immunization and infection control. Ultimate responsibility lies with the chief executive of each health authority, health board or National Health Service.
trust. UK medical students undertaking “electives” in developing countries may be at particular risk, as will inexperienced hospital porters handling sharps containers on a regular basis.

To assist in this important process, the BMA Board of Science and Education has produced an interactive CD-ROM that covers all the major issues, concerned with bloodborne viruses/infection control and is suitable for universities and colleges, hospitals and general practices (Morgan, 1999). This CD-ROM will supplement locally produced guidelines and provide users with:

- a basic introduction to HIV, HBV, and HCV;
- information on protective clothing and safe use and disposal of sharps;
- emergency advice following sharps injury and post-exposure treatments;
- comprehensive information on instrument sterilisation, disinfection and clinical waste in primary care;
- case studies from leading journals and a searchable bibliographical database; and
- technical information from the UK Health and Safety Executive and Medical Devices Agency and the full searchable text of the recent guidelines from the Department of Health.

The CD-ROM contains numerous graphics and video clips, is easy to use and navigate and can be used on stand-alone personal computers or run on networked systems, perhaps as part of an hospital health and safety database resource. Injured staff should be able to access the system on a 24 hour basis to obtain immediate guidance following an exposure.

DISCUSSION

Prior to the introduction of HBV vaccine and improved health and safety legislation, thousands of hospital staff became infected worldwide each year with this virus. With the emergence of new strains of viral hepatitis, and the absence of vaccines for HIV and HCV, the risk of infection to healthcare staff will persist. The routine use of needles and other sharps will continue to pose hazards and improved reporting and audit shows that staff still experience high rates of sharps injuries.

Concern about HIV has not led to a substantial reduction in sharps injuries. In contrast, the reductions reported in the literature are correlated with changes in staff education and procedures (Dale, 1998), including:

- All “at risk” staff must receive appropriate training, as part of an induction before they are routinely in contact with sharps;
- Staff “at risk” must be provided with suitable protective clothing, hepatitis B immunisation and access to occupational health services;
- All medical schools and hospitals should actively discourage staff and students from resheathing contaminated needles and recommend that syringes/needles be disposed of intact, directly after use, into an approved container;
- A plentiful supply of approved sharps containers must be provided in all theatres, clinical departments, accident and emergency areas, hospital wards, etc. and emptied regularly;
- Reporting of all sharps injuries must be actively encouraged, regular audits carried out and staff provided with “refresher training”; and
- Injured staff should receive medical advice, counselling and in the case of high risk exposure for HIV, Post Exposure Prophylaxis should be considered. All healthcare facilities should have policies to deal with any member of staff who may become infected in the course of their work.

The style of staff training and support should be tailored according to its objectives. Large meetings provide a useful format for conveying information about bloodborne pathogens and infection control principles but do not encourage discussion of attitudes and anxieties, especially with multidisciplinary groups. Small meetings, particularly of people working together, should provide a more suitable environment for expressions of uncertainty. Discussions could cover techniques, practices, or previously unspoken concerns about lack of an adequate infection control policy or resources. Posters, such as that in Figure 1, can be effective.

The outcome of staff training and communication needs to be evaluated in terms of the effect on staff knowledge and attitudes but especially on staff behaviour in infection control practices. A hospital “culture” may exist in which reporting of a sharps injury or blood exposure is not encouraged as this would reflect badly both on the individual, who could be seen to be incompetent or making a fuss, and also on the supervisor. This could become particularly noticeable if assessment of a student after an exposure is badly managed, or if a blood sample is required to be taken from a pa-
FIGURE 1
Model principles for handling sharps—a poster for use in all health care settings. (Source: BMA)

FOLLOW THE SIMPLE RULES BELOW:

- You used it – you bin it
- Do not resheathe needles
- Discard needle and syringe as one unit
- Dispose of sharps into a safe container, immediately after use
- Do not leave used sharps lying around
- Do not overfill sharps containers
- Report all sharps injuries
- Get immunised against hepatitis B

British Medical Association
guidelines on Bloodborne Viruses and Infection Control now on interactive CD ROM. To order: Tel. BMJ Bookshop 0207-383-6244
tient who may not be agreeable. Reporting of exposures must be encouraged and an effective system of follow-up must be established.

Over the years we have seen that education and guidelines will not in themselves bring about changes in healthcare worker behaviour, but new methods to impart information such as interactive CD-ROM systems or the use of role playing and problem-solving educational techniques should be fully examined. Improved clinical safety and infection control will be dependent on the necessary physical environment and the attitudes of senior staff, who must provide the resources and motivation to manage the use and disposal of sharps more safely in all clinical environments.

The CD-ROM described in this report requires a 486 PC with 12 Mb RAM, Microsoft Windows 3.1 or later (Windows 95 or later and 4XCD drive recommended) and SVGA graphics, minimum 65K colors, with sound card and speakers.

To order, please contact the BMJ Bookshop at BMA House, Tavistock Square, London, UK, WC1H 9JR (Fax: (0)-207-383-6455 or by e-mail at orders@bmjbooks.com). Single user price = £42 or site licence with three CDs at £195 (both require payment of VAT at 17.5%). In addition, one must add 30% to the total cost for postage and handling fees.

REFERENCES


MEDICAL AND INFECTIOUS WASTE MANAGEMENT

Ira F. Salkin\textsuperscript{1}, Edward Krisiunas\textsuperscript{2}, and Wayne L. Turnberg\textsuperscript{3}
\textsuperscript{1}New York State Department of Health, Albany, New York; \textsuperscript{2}Sharps Consulting, Burlington, Connecticut; \textsuperscript{3}University of Washington, Seattle, Washington

This article was originally published in Anthology of Biosafety II: Facility Design Considerations, chapter 10, pp. 140-160, © 2000.

ABSTRACT

There is no uniform national standard for defining the wastes that comprise the regulated medical waste (RMW) stream. Based on the variability associated with infectious disease causation, no method exists to determine the potential "infectivity" posed by RMW. Because of this, regulated medical waste definitions developed by the various federal, state, and local government entities are based on the agencies' judgments of risk from the perspective of the jurisdiction to which the definition will apply. It then becomes the responsibility of the regulated community to recognize the various agencies with jurisdiction over definitions and to address the definitional elements of each, recognizing and addressing the inconsistencies that may exist.

Definitions of Regulated Medical Waste

While RMW has never been linked to the transmission of an infectious disease to a member of the public (Rutala and Mayhall, 1992), it was recently associated with an outbreak of tuberculosis at a commercial RMW treatment facility operating in Washington state (Weber, et al, 1999). Three workers at the site were diagnosed with active tuberculosis, and 13 other employees at the facility demonstrated positive conversion reactions with the tuberculin skin test. Since each of the isolates of the etiologic agent recovered from the active cases showed different antibiotic susceptibility patterns, there is little chance of person-to-person transmission of the infection among these employees. Although the specific mechanism for disease transmission could not be identified within the facility, one isolate was linked by DNA fingerprinting to a culture from a clinical laboratory that had been sending its waste to the facility for treatment. While such occurrences are rare, it highlights the potential infection risk associated with improper handling of this waste stream.

Regulated medical waste definitions should be developed recognizing the elements necessary for infectious disease transmission, e.g., (1) the type, virulence and concentration of pathogen, (2) the susceptibility of the host, (3) the method of transmitting the organism to the host, (4) the infective dose of the pathogen, and (5) the portal of entry into the host.

Federal Definitions

At least five federal agencies have established regulated medical waste definitions, each with a different approach or need. These agencies include the US Environmental Protection Agency (EPA; 40 CFR Part 60.51c), the US Department of Transportation (DOT; 49 CFR Part 173.134), the Occupational Health and Safety Administration (OSHA; 29 CFR Part 1910.1030[b]), the United States Postal Service (USPS; 39 CFR Part 111.1), and the US Public Health Service (PHS; 42 CFR Part 72.3). In addition, guidance documents have been developed by the Centers for Disease Control and Prevention (CDC; Garner and Favero, 1985), and the EPA (EPA/530-SW-86-014, 1986).

The EPA has adopted a "list based" approach in defining RMW (termed medical infectious waste) to be incinerated in a medical waste incinerator, as published at 40 CFR Part 60.51c. It includes wastes falling into the specific categories of cultures and stocks, human pathological waste, human blood and blood products, sharps, certain animal waste involving animals that were known to have been exposed to infectious agents during research, and certain isolation wastes involving highly communicable diseases. The EPA definition states:

Medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that is listed in paragraphs 1 through 7 of this definition. The definition does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as
defined in 261.4 (b) (1) of this chapter; ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains and anatomical parts that are intended for internment; and domestic sewage materials identified in 261.4 (a) (1) of this chapter.

1. Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

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

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

4. Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

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

6. Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

7. Unused sharps including the following unused, discarded sharps; hypodermic needles, suture needles, syringes, and scalpel blades.

In contrast to the EPA definition, the DOT has adopted a "criteria based" approach in defining wastes subject to inter and intrastate transportation requirements, which has lead to uncertainty in its interpretation. The DOT definition, termed regulated medical waste, as published at 49 CFR Part 173.134, states:

A regulated medical waste means a waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in; (1) the diagnosis, treatment or immunization of human beings or animals; (2) research pertaining to the diagnosis, treatment or immunization of human beings or animals; or (3) the production or testing of biological products.

In its transportation standard, the DOT makes a definitional distinction between RMW and infectious substances, and applies different regulatory restrictions on the packaging and transport of each. The DOT defines infectious substances at 49 CFR Part 173.134 (a) (1) as follows:

An infectious substance means a viable microorganism, or its toxin, that causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Seances and any other agent that causes or may cause severe disabling or fatal disease. The terms infectious substance and etiologic agent are synonymous.

The Occupational Safety and Health Agency has published a definition, which is termed regulated waste at 29 CFR Part 1910.1030, paragraph (b). The OSHA definition, which is specific to the blood borne pathogen standards, is a follows:

“Regulated Waste” is specifically defined to include only wastes that meet the following tests:

1. Liquid or semi-liquid blood or other potentially infectious materials;
2. Contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed;
3. Items that are caked with blood or other potentially infectious materials and are capable of releasing these materials during handling;
4. Contaminated sharps; and
5. Pathological and microbiological wastes containing blood or other potentially infectious materials.

The following elements within the OSHA definition of "regulated medical waste" must be considered by employers when making decisions regarding applicability of the rule to their institution:

1. "Blood" is defined to mean "Human blood, human blood components, and products made from human blood."
2. "Contaminated" means "The presence or the reasonably anticipated presence of blood or other potentially
infectious materials on an item or surface"

3. "Other Potentially Infectious Materials" means "The following human body fluids; semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids," and

4. "Contaminated Sharps" means "Any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires."

Other potentially infectious materials, e.g., vomitus, sputum, feces or urine, that are not associated with bloodborne diseases have not been included within the scope of the bloodborne pathogen rule's definition of "regulated waste." However, if these materials contain visible blood, they would be subject to the standards of the bloodborne pathogen rule.

In 1985, the CDC published "Guideline for Handwashing and Hospital Environmental Control" (Garner and Favero), in which it recommends the following for the handling of infective waste:

There is no epidemiologic evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiologic evidence that hospital waste disposal practices have caused disease in the community. Therefore, identifying wastes for which special precautions are indicated is largely a matter of judgment about the relative risk of disease transmission. Aesthetic and emotional considerations may override the actual risk of disease transmission, particularly for pathology wastes.

In its recommendation, the CDC noted the difficulty and inappropriateness of categorizing a waste as infective waste based on quantity and types of etiologic agents present. The CDC therefore based its infective waste definition on identifying wastes that represent a sufficient potential infection risk during handling and disposal, and for which special precautions may be prudent. The wastes recommended by the CDC as being potentially infective include:

1. Microbiology laboratory wastes;
2. Pathology wastes;
3. Blood specimens or blood products; and
4. Certain sharp items (e.g., needles and scalpel blades)

Furthermore, the CDC noted that although certain wastes may be contaminated with potentially infective blood, secretions, excretions, or exu-dates, it is not necessary to treat such waste, unless it is contaminated with certain rare disease-causing agents, such as Lassa virus.

A general comparison of federal regulated medical waste definitions established in both regulation and guideline is presented in Table 1.

State Definitions

In addition to addressing the applicable federal definitions, the regulated community must also consider the definitions developed by state legislatures and governments. In the United States, definitions have been established by 48 state governments, each marked by its individuality. Many terms for RMW have been used in these statutes and regulations, e.g., infectious waste, biohazardous waste, biomedical waste, potentially infectious biomedical waste, biological waste, medical waste, potentially infectious medical waste, and controlled regulated medical waste. However, throughout this chapter we will continue to use RMW in place of all of these descriptive terms. Although state definitions can be highly variable in their language and approach, five categories of regulated medical waste are routinely identified in the definitions. For example, 46 states include a definition for "stocks and cultures" waste, 43 for "sharps" waste, 45 for "human blood and blood products," 42 for "pathological waste," and 35 for "animal waste" when derived from animals infected with human pathogens in the course of research.

Working Definition

Based on the principles of disease transmission, the following broad categories of waste are recommended for special handling and disposal as RMW:

1. Cultures and stocks of infectious agents and associated biologicals: Cultures and stocks of infectious agents and associated biologicals may include such wastes as specimens from medical and pathology laboratories, cultures and stocks of infectious agents from clinical, research, and industrial laboratories, disposable culture dishes and devices used to transfer, inoculate, and mix cultures, wastes from production of biologicals, and discarded live and attenuated vaccines (EPA/530-SW-86-014). Microbiology laboratories grow human disease-causing etiologic agents in high concentrations on artificial media for the purposes of propagation, identification, and research. This waste category presents an infection hazard due to its
TABLE 1
Comparison of Federal Infectious Waste Definitions

<table>
<thead>
<tr>
<th>Material</th>
<th>EPA&lt;sup&gt;a&lt;/sup&gt; Regulation</th>
<th>DOT&lt;sup&gt;b&lt;/sup&gt; Regulation</th>
<th>OSHA&lt;sup&gt;c&lt;/sup&gt; Regulation</th>
<th>USPS&lt;sup&gt;d&lt;/sup&gt; Regulation</th>
<th>PHS&lt;sup&gt;e&lt;/sup&gt; Regulation</th>
<th>CDC&lt;sup&gt;f&lt;/sup&gt; Guideline</th>
<th>EPA&lt;sup&gt;g&lt;/sup&gt; Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cultures and stocks</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Pathological waste</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Human blood and blood products</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sharps</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Contaminated animal waste</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Isolation waste</td>
<td>Yes</td>
<td>Yes&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Yes&lt;sup&gt;3&lt;/sup&gt;</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

(a) US Environmental Protection Agency (See EPA 40 CFR Part 60.51c)
(b) US Department of Transportation (See DOT 49 CFR Part 173-134)
(c) Occupational Health and Safety Administration (See OSHA 29 CFR 1910.1030[b])
(d) United States Postal Service (See USPS 39 CFR part 111.1)
(e) Public Health Service (See USPHS 42 CFR Part 72.3)
(f) Centers for Disease Control and Prevention (See Garner and Favero, 1985)
(g) US Environmental Protection Agency (See EPA/530-SW-86-014)
(h) Regulated as an infectious substance.
(i) Any medical waste other than cultures and stocks containing an infectious substance generated in the course of medical care.
(j) Isolation wastes containing blood or other potentially infectious materials.
(k) Any device used in medical practice that does not contain a sharp.

High concentration of microbial agents. Occupational infection among laboratory workers is well documented in the scientific literature, although such infections have not been attributed to contact with waste per se (Barkely, et al, 1983; Pike, 1976; Pike, 1979). Both the CDC (Garner and Favero, 1985) and the EPA (EPA/530-SW-86-014) have recommended in their guidelines that these wastes be inactivated prior to disposal.

2. **Sharps waste**: Sharps waste may include medical waste such as hypodermic needles, syringes, Pasteur pipettes, or scalpels blades that have been used in animal or human patient care, treatment, or research. Sharps present safety and disease transmission hazards because of their ability to create a portal of entry through the skin, as well as carry potentially infectious agents. Infectious disease transmission resulting from needlestick injuries to medical practitioners during the course of healthcare is well documented in the scientific literature (Bock, et al, 1981; McCormick and Maki, 1981; Jagger, et al, 1989). Injuries have also been observed among non-medical occupational groups, particularly in the waste collection industry (Turnberg and Frost, 1990).

3. **Waste human blood and blood components**: This category may include liquid waste human blood and blood products, items saturated and/or dripping with human blood, or items that are caked with dried human blood, and other blood components such as serum or plasma. Infectious disease transmission has been implicated among healthcare workers due to inadvertent contact with human blood through exposure to skin breaks or abrasions, or mucous membranes (CDC, 1987).

4. **Human pathological waste**: This waste category may include tissues, organs, and body parts that are removed during surgery or autopsy. Although pathological waste has not been implicated in disease transmission in the scientific literature, both the CDC and EPA designate this waste as having potentially infective qualities and recommend special handling and treatment prior to disposal. Improper disposal of pathological waste is also aesthetically
unacceptable (Garner and Favero, 1985 and EPA/530-SW-86-014).

5. **Animal waste**: This category may include animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research, including research in veterinary settings. Although this waste stream has not been implicated in disease transmission to humans, the waste by definition is the result of artificially inoculating animals with etiologic agents infectious to humans, and warrants special disposal considerations.

### Management of Regulated Medical Waste

The first section of this chapter provided insights into the variety of regulations and definitions of RMW facing healthcare providers. In establishing a RMW management program, standards of practice will often be dictated by the regulations of the geographic region in which the generator is located. Before initiating such a program, obtain and review all pertinent local and state regulations, as well as be aware of regulations in other jurisdictions, especially when offering infectious waste for offsite treatment in another state.

The approach described in Annex 1 is analogous to a health care provider obtaining a history and performing an initial physical on a patient to establish the diagnosis and appropriate therapy. In addition to establishing objectives, (I. Objective), one must also review appropriate regulations (II. Regulatory Review) which will assist the reviewer/auditor in determining whether items observed during the audit (III. Conduct Audit of Present Regulated Medical Waste Management Program) meet with regulatory requirements. The findings will dictate what type of corrective action, if any, is necessary (IV. Provide Assessment and Recommendations). For example, additional containers may be required to collect and store non-contaminated glassware that otherwise would have been disposed of as RMW. Smaller RMW containers, as another example, may be needed in areas in which limited quantities of RMW are generated. It would be important to obtain items to be used for waste collection, e.g., trash receptacles, before providing training to staff to demonstrate appropriate disposal methods (V. Develop and Implement Program Components). It is essential, as the management plan is implemented in all areas of the facility, to monitor its adoption by staff in order to enforce compliance and provide appropriate feedback to demonstrate the plan’s cost benefits. An excellent example of the benefits to be obtained from an effective waste management plan was recently described in a report by Garcia based upon his work at the Brookdale Hospital and Medical Center (Garcia, 1999). Readers will find this recent reference of great assistance as they develop their own procedures to manage and hopefully decrease the generation of RMW in their own facilities.

One key element in the management plan is the on-site packaging of the RMW, which can be divided into three basic areas:

1. **Sharps**

   All sharps should be packaged in leakproof, rigid, puncture resistant containers with lids in place which may be secured to preclude loss of contents. They should be located in all areas in which sharps may be generated to allow for their immediate disposal to reduce the risk of injury. Additionally, the size of the containers should be appropriate to the area within the facility in which they are located, e.g., laboratory, emergency department, and patient care areas.

2. **Body Fluids/Liquids**

   Disposal of body fluids and liquids may present problems due to potential occupational exposures to the liquids when the containers are emptied. Although solidifying agents can be added to reduce the risk of exposure and to limit possible leaking of the contents, personal protective equipment should be used by all employees when disposing of liquids in a manner permitted by local and state regulations.

3. **Other than sharps/liquids**

   All other RMW should be placed into rigid, puncture resistant hard sided containers lined with red bags or as required by applicable regulations. In most states, both the red bags and the outer rigid containers should be labeled with a phrase such as “infectious, biohazard” or “regulated medical waste.”

   It should not be forgotten that collection systems for non-RMW solid and liquid waste should be immediately available and strategically located so as to limit the volume of such waste entering the RMW waste stream.

### Treatment of Regulated Medical Waste

Incineration and autoclaving are the most widely employed methods of RMW treatment. The
numerous advantages associated with incineration (Table 2) and its long history as an effective method of waste management have lead to worldwide use as the preferred means of treating and disposing of medical waste. However, growing problems with air pollution, among other disadvantages to its application in medical waste treatment (Table 2), have caused many government and state regulatory agencies to introduce more stringent air-quality standards (Barkley, et al, 1983). Healthcare and other facilities which generate medical waste, have found that to meet these enhanced requirements through retrofitting existing incinerators or purchasing new equipment would be cost-prohibitive and have simply deactivated their incinerators. For example, in 1990, there were approximately 150 medical waste incinerators in operation at hospitals, nursing homes, laboratories, and commercial facilities in New York State. However, by 1999, there were only 12 incinerators in use at healthcare facilities within the state.

Since 1876, when Charles Chamberland built the first pressure steam sterilizer, autoclaves have been used for the sterilization of surgical instruments, medical devices, heat stable liquids, as well as numerous applications in clinical laboratories and private industry. Therefore, it was a natural progression to utilize autoclaves to decrease or eliminate the potential bioburden contained in medical waste. While autoclaving of medical waste does offer several advantages over incineration, there is a “downside” to its application in processing both liquid and solid forms of this waste (Table 2). One major concern associated with the use of autoclaves which has been overlooked until relatively recently has been the generation of potentially hazardous chemicals. Since pressurized steam is an excellent method of volatilizing organic compounds, and many organic reactions are accelerated at elevated temperatures, a wide variety of organic species maybe emitted depending upon the quantity and composition of the hazardous chemicals contained in the waste. Further, autoclaves cannot be used to treat a wide variety of waste, e.g., radioactive, chemotherapeutic, and pathologic waste. Finally, even with the newer vacuum systems, effective treatment of this very narrow range of waste in an autoclave requires one to one and one-half hours. The net result of these restrictions has been a decrease in the use of autoclaves to treat large quantities of laboratory waste (Joslyn, 1991; Turnberg, 1996).

The reduction in the use of incinerators and the limitations on the application of autoclaves have created a new industry-alternative medical waste treatment systems. Currently, there are over 40 such technologies available from greater than seventy manufacturers within the United States, Europe, the Middle East, and Australia (Pike, 1979; Annex 2). While these systems vary in their treatment capacity, the extent of automation, and overall volume reduction, all alternative technologies utilize one or more of the following methods: (1) heating the waste to a minimum of 90-95°C by means of microwaves. radio waves, hot oil, hot water, steam, or superheated gases; (2) exposing the waste to chemicals such as sodium hypochlorite (household bleach) or chlorine dioxide; (3) subjecting the waste to heated chemicals; and (4) exposing the medical waste to irradiation sources.

Thermal systems which use heat to inactivate pathogenic microorganisms are the most common alternative technologies for the treatment of medical waste. These systems can be broadly divided into those using low temperatures, e.g., 95°C (moist heat) to 250°C (dry heat) and those that use high temperatures, e.g., approximately 500°C to greater than 6,000°C. The latter systems combust and destroy the waste as part of the treatment process. The most frequently used heat inactivation systems are (see Annex 2 for information on the manufacturers, capacities, treatment cycles, and states in which the systems are approved to be sited, as well as Joslyn, 1991 and Salkin and Krisiunas, 1998 for additional details) as follows:

1. **Low-Temperature Systems - Microwaves**
   Microwaves are defined as those with a frequency in between radio and infrared waves in the electromagnetic spectrum. When used in the treatment of medical waste, they stimulate the preshredded and moistened waste to generate heat (95°C) and release steam. It is the combination of the microwaves and moisture which is required to generate the thermal energy to effectively treat the medical waste, e.g., Sanitec.

2. **Low-Temperature Systems - Macrowaves**
   Some systems apply low-frequency radio waves to heat shredded, moistened, compacted clinical waste to 90°C for an extended period of time, thereby inactivating microbes contained within the waste, e.g., Stericycle.

3. **Low-Temperature Systems - Dry Heat**
   Several treatment systems available for
### TABLE 2
Advantages and Disadvantages of Common Clinical Waste Treatment Systems

<table>
<thead>
<tr>
<th>Type</th>
<th>Factors</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incineration</td>
<td>Turbulence and mixing&lt;br&gt;Moisture content of waste&lt;br&gt;Filling combustion chamber&lt;br&gt;Temperature and residence time&lt;br&gt;Maintenance and repair</td>
<td>Volume and weight reduction&lt;br&gt;Unrecognizable waste&lt;br&gt;Acceptable for all waste types&lt;br&gt;Heat recovery potential</td>
<td>Public opposition&lt;br&gt;High investment and operation costs&lt;br&gt;High maintenance cost&lt;br&gt;Future restrictive emissions laws</td>
</tr>
<tr>
<td>Steam Autoclave</td>
<td>Temperature and pressure&lt;br&gt;Steam penetration&lt;br&gt;Size of waste load&lt;br&gt;Length of treatment cycles&lt;br&gt;Chamber air removed</td>
<td>Low investment cost&lt;br&gt;Low operating cost&lt;br&gt;Ease of biological tests&lt;br&gt;Low hazard residue</td>
<td>Appearance, volume unchanged&lt;br&gt;Not suitable for all waste types&lt;br&gt;Air emissions Ergonomic concerns</td>
</tr>
<tr>
<td>Microwave</td>
<td>Waste characteristics&lt;br&gt;Moisture content of waste&lt;br&gt;Microwave strength&lt;br&gt;Duration of exposure&lt;br&gt;Extent of waste mixture</td>
<td>Unrecognizable waste&lt;br&gt;Significant volume reduction&lt;br&gt;Absence of liquid discharge</td>
<td>High investment cost&lt;br&gt;Increased waste weight&lt;br&gt;Not suitable for all waste types&lt;br&gt;Air emissions Ergonomic concerns</td>
</tr>
<tr>
<td>Mechanical/Chemical</td>
<td>Concerns for chemicals, temperature, pH&lt;br&gt;Chemical contact time&lt;br&gt;Waste and chemical mixing Recirculation vs flow-through</td>
<td>Significant volume reduction&lt;br&gt;Unrecognizable waste&lt;br&gt;Rapid processing&lt;br&gt;Waste deodorization</td>
<td>High investment cost&lt;br&gt;Not suitable—all waste types&lt;br&gt;Air emissions&lt;br&gt;Need for chemical storage&lt;br&gt;Ergonomic concerns</td>
</tr>
<tr>
<td>Pyrolysis</td>
<td>Waste characteristics&lt;br&gt;Temperature&lt;br&gt;Length of treatment cycle</td>
<td>Almost no waste remains&lt;br&gt;Unrecognizable waste&lt;br&gt;Heat recovery potential</td>
<td>Novel technology&lt;br&gt;Air emissions must be treated&lt;br&gt;Skilled operator needed</td>
</tr>
</tbody>
</table>

large (e.g., hospitals) and small-quantity generators (e.g., physician/dental offices) thermally inactivate potentially pathogenic microorganisms through the use of electrically generated heated air, oil, or molten plastic, e.g., Medi-waste.

4. **High-Temperature Systems - Pyrolysis**

Pyrolysis involves the high temperature (545 to 1,000°C) treatment of waste in the absence of oxygen. In generating these high temperatures, the systems treat, destroy and reduce the volume of clinical waste, e.g., Plasma Energy Pyrolysis System (PEPS).

5. **High-Temperature Systems - Plasma Technology**

In a plasma system, an electric current is used to ionize an inert gas (e.g., argon) to cause the formation of an electric arc to create temperatures as high as 6,000°C. The medical waste within the system is brought to temperatures between 1,300 to 1,700°C, destroying potentially pathogenic microbes and converting the waste into a glassy rock or slag, ferrous metal, and inert gases, e.g., Peat’s Plasma Arc Reactor System.

Chemical treatment systems have an extensive and well-documented history in the clinical setting in disinfecting and sterilizing environmental surfaces and medical devices (Jagger, et al, 1989). Inherent in the operation of such systems is the fact that the waste must first be shredded prior to exposure to such agents as sodium hypochlorite, chlorine dioxide, peracetic acid, glutaraldehyde, quaternary ammonium compounds, etc., in order to bring all surfaces of the waste into direct contact with
the chemicals. Some systems combine heat with the chemicals to reduce the length of the treatment cycle. One of the newer chemical systems, Waste Reduction by Waste Reduction or WR$^2$, utilizes hot 1N sodium hydroxide under pressure to treat animal carcasses and reduce this form of pathological waste to bone meal. Additionally, recent information in the literature would indicate that, in theory, the WR$^2$'s use of heated chemicals under pressure would allow for the effective treatment of Prion contaminated waste. If this is verified through scientific investigations, it would mean that the WR$^2$ is the only system, including incinerators, which is capable of treating waste generated through treatment of human and animals infected with Prion, e.g., “mad cow’s disease.”

The selection of the most appropriate system depends upon the composition of the medical waste, the volume of waste to be treated, staffing requirements for the system in terms of both numbers and education levels of employees, support capabilities of the vendor, and initial and continuing operating costs. Several critical factors which should be considered in the selection of an alternative treatment technology are (see Pike, 1979 for more detailed information):

1. **Treatment Capabilities**

   While some treatment systems are specifically designed to process only one type of waste component, e.g., sharps, liquids, animal byproducts, most commercially available systems can treat several different components of the medical waste stream. Obviously, the more types of waste, e.g., pathologic, chemotherapeutic agents, radioactive materials, etc., that can be processed by the system, the simpler it is to operate, since the medical waste stream does not have to be segregated into its specific components for treatment. Consequently, one key criterion in selecting a medical waste treatment system is to match the capabilities of the technology to the types of waste generated by the facility.

2. **Grinding/Shredding**

   While, as noted, grinding/shredding of medical waste is a necessary first step in chemical treatment systems, other types of treatment technologies may also employ such devices for one or more of the following reasons:
   a. reduce the volume of waste;
   b. remove or reduce physical hazards; and
   c. render the waste unrecognizable.

Although compaction of the waste is used with a few treatment systems, it is generally less efficient than shredding/grinding and must generally be employed after treatment, as the compacting process might generate infectious aerosols.

In addition, emergency support capabilities of the vendors is another important selection criterion. In treatment systems that employ grinders/shredders at the end of the cycle, vendors should be able to provide information and physical assistance, if needed, to store the treated waste until repairs can be completed. If the grinders/shredders are used prior to treatment, vendors must be able to indicate proper decontamination methods for the waste so as to prevent the waste from being a physical and biological hazard to the operators and environment.

3. **Process Capacity**

   Process capacity may be defined as the volume of waste that may be treated by a system per unit of time. There are commercially available treatment systems with process capacities as low as one syringe per minute to those with capacities as high as 3,000 pounds (approximately 1,360 kilograms) of waste per hour. Further, some systems require a minimum charging capacity, e.g., a minimum volume of waste for the system to operate effectively. In selecting a treatment system, consideration must be given to sizing the technology to the volume of waste generated by the facility.

4. **“Throat” Capacity**

   “Throat” capacity refers to the size and/or volume capacity of the aperture through which the medical waste enters the treatment systems. As in process capacity, treatment technologies vary as to volume, size, and types of waste that can be introduced into the system. Restrictions in a system's throat capacity might require excessive waste handling, which in turn could cause increase operating costs and create safety problems. While an important selection criterion, throat capacity is not often considered in evaluating treatment systems.

5. **Vendor Responsibilities**

   In selecting a system, vendors should be required to provide efficacy test data to support claims of the technology's treatment capabilities. Prior to accepting a treatment system,
the vendors should conduct initial validation tests to demonstrate that the system's on-site capabilities are identical with those found during the technology's initial efficacy tests. Additionally, the vendor should have satisfied all governmental regulatory requirements. Finally, "sampling ports," a feature of some treatment technologies, greatly simplify quality control test procedures. These ports provide openings into the system through which samples of the treated or untreated waste may be collected on a periodic basis for testing to ensure that the technology is operating effectively.

6. Air Emissions

Particulate and potentially toxic air emissions from incinerators are the primary factors that contributed to the development of alternative treatment technologies. Uncontrolled air emissions may lead to the release of potentially hazardous and/or toxic materials in such a manner that ambient concentrations become excessive. If emissions are generated during the treatment cycle, they should not be hazardous or toxic; or, if these sorts of emissions are released, the treatment system should have abatement equipment to reduce the levels of toxic/hazardous substances. If emissions are vented to the outside, it is critical that they be:

a. colorless and free from persistent mist or droplets;

b. odorless as detectable at the boundaries of the facilities; and

c. vented, when appropriate, through High Efficiency Particulate Air (HEPA) filters.

Proper installation and effectiveness of HEPA filters must be verified using existing standard (DOP; dioctyl phthalate particles) tests and their operations monitored with a magnahelic or other pressure differential measuring device. HEPA filters should only be removed by trained personnel and disposed of as medical waste.

Transport of Regulated Medical Waste

The DOT divided the universe of discarded infectious substances, under 49 CFR Parts 173 and 178 into two separate categories—Regulated Medical Waste and Discarded Cultures and Stocks (MWI, 1999). While both of types of waste are classified as hazardous materials, the DOT considers that the transportation of cultures and stocks poses a higher level of risk. Consequently, the DOT established the following distinct packaging standards for each of these waste streams:

1. Regulated Medical Waste

Private carriers transporting regulated medical waste (RMW) are exempt from the specific packaging requirements of 49 CFR 173.197 provided they package the waste in containers that comply with DOT's General Packaging Standards (49 CFR 173.24 and 173.24a), as well as the packaging standards prescribed by OSHA in the bloodborne pathogens standard (29 CFR Part 1910.1030b).

Each package used for the shipment of RMW must be designed, constructed, maintained, filled, and closed, such that under normal conditions of transportation, including the effects of temperature and vibration, there is no identifiable release of hazardous materials to the environment. Packages must be closable, rigid, puncture resistant, leakproof on the sides and bottom, and labeled with the OSHA biohazard symbol.

2. Cultures and Stocks of Infectious Substances

Under 49 CFR 173.134 (c) (4), discarded cultures and stocks of Biosafety Levels 2 and 3 (Center for Disease Control 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, May 1999, Section II) potentially infectious organisms must be packaged in containers which are; (1) rigid, (2) leak resistant, (3) impervious to moisture, (4) of sufficient strength to prevent tearing or bursting under normal conditions of use and handling, (5) sealed to prevent leakage during transport, (6) puncture resistant for sharps and sharps with residual fluids, and (7) break-resistant and tightly lidded or stoppered for fluids in quantities greater than 20 cm².

In addition, the packaging must be capable of passing the following DOT Group II performance requirements:

1. Drop Test

Samples must be subjected to free-fall drops onto a rigid, nonresilient, flat, horizontal surface from a height of 1.2 m (3.9 feet; 49 CFR 178.603);

2. Stacking Test

Packaging must be subjected to a force applied to the top surface of the test sample equivalent to the total weight of identical packages which might be stacked on it during transport. The minimum height of the stack, includ-
ing the test sample, must be 3.0 m (10 feet) and the duration of the test must be 24 hours. However, plastic drums, jerri-cans, and composite packaging, intended for liquids, must be subjected to the stacking test for a period of 28 days at a temperature of not less than 40°C (104°F; 49 CFR 178.606);

3. Vibration Test

Each package must be capable of withstanding, without rupture or leakage, the vibration test, where sample packages are placed on a vibrating platform that has a vertical or rotary double-amplitude (peak-to-peak displacement) of one inch, for a period of one hour. A package passes the vibration test if there is no rupture or leakage. No test sample should show any deterioration which could adversely affect transportation safety or any distortion liable to reduce packaging strength;

4. Leakproof Test

The package must be restrained under water while internal air pressure, of not less than 20 kPa (3 psi) is applied for five minutes (49 CFR 178.604);

5. Hydrostatic Pressure Test

The hydrostatic pressure test must be conducted for the qualification of all metal, plastic, and composite packaging design types intended to contain liquids, but not for inner packages of combination packaging (49 CFR 178.605).

The DOT requires (49 CFR 172.300 et. seq.) the generator to mark each package containing RMW which is to be transported off-site for treatment with the proper shipping name (Regulated Medical Waste) and identification number (UN 3291) and these markings must be:

1. Durable, written in English, and printed on or affixed to the surface of the package or on a label, tag, or sign;
2. Displayed on a background of sharply contrasting color;
3. Unobscured by labels or attachments; and
4. Located away from any other marking (such as advertising) that could substantially reduce its effectiveness.

Additionally, DOT requires the transporter (49 CFR 172.400 et. seq.) to have an infectious substances label (49 CFR 172.432) printed on or affixed to a surface (other than the bottom) of the RMW package. The durable and weather resistant label must be located on the same surface as and near to the proper shipping name marking. However, it must be noted that private and contract carriers are exempt from the infectious substance label requirements provided that the package is either color coded (red bags or red containers) or marked with a fluorescent orange BIOHAZARD marking in accordance with OSHA regulations found in 29 CFR 1910.1030.

While DOT and EPA require manifests for the transport of hazardous waste, neither include RMW as part of this requirement. However, most states do have some form of manifest regulations and readers should consult their own state’s regulatory agency as to their responsibilities for tracking RMW.

One of the least known DOT requirements for RMW transport is that contained in 49 CFR 172.600 et. seq. concerning emergency response in the event of spills and accidents. Specifically the regulations stipulate that any person who offers for transportation, accepts for transportation, transfers, stores, or otherwise handles RMW during transport must have the following information immediately available:

1. The basic description and technical name (Regulated Medical Waste) of the hazardous material;
2. A list of the health hazards posed by the RMW;
3. A description of the risks of fire or explosion which might be created by the RMW;
4. Immediate precautions to be taken in the event of an accident or incident;
5. Immediate methods for handling fires;
6. Initial methods for handling spills or leaks in the absence of fire;
7. Preliminary first aid measures; and
8. Telephone response information.

Relative to the telephone response, 49 CFR 172.604 requires the generator to provide a 24-hour emergency response telephone number (including the area code or international access code). The telephone number must be monitored at all times the RMW is in transport, including storage incidental to transportation, by a person (not an answer machine or similar device) who has comprehensive emergency response information for regulated medical waste. The emergency response number must be entered on the shipping papers in a clearly visible location.
Summary

In the absence of a uniform national code of regulations for defining medical wastes, the generator is left with the need to ensure compliance with those federal, state and local regulations that apply to their particular facility. This chapter has collected together the current available applicable information to assist in this process.

REFERENCES


ANNEX 1
Regulated Medical Waste Management Program

I. Objectives
   A. Assess present RMW program to define problem areas
   B. Develop program to address problem areas
   C. Implement program to correct problems
   D. Monitor and enforce compliance and provide feedback to staff

II. Regulatory Review
   A. USEPA - Medical Waste Tracking Act
   B. State Regulatory Review (Department of Environmental Protection/Department of Health)
   C. OSHA - Bloodborne Pathogen Standard - 1910.1030
   D. USDOT - HM-181/Other regulatory issues
   E. CDC Guidelines (Biosafety in Medical and Biomedical Laboratories)
   F. NIH Guidelines for Research Involving Recombinant DNA Molecules
   G. Other applicable regulations and guidelines

III. Conduct Audit of Present RMW Program
   A. Present program
      1. Policy
      2. Education
      3. Method
      4. Management

IV. Provide Assessment and Recommendations
   A. Assessment/Recommendations
      1. Policy
      2. Education
      3. Method
      4. Management

V. Develop and Implement Program Components
   A. Facility Wide Program or Area Specific
      1. Education
         a. Methods available
            1) Unit based program: Training conducted in all patient care areas and departments
   2) Training conducted in a central meeting area
   3) Train the trainer/Other
   b. Personnel to Train
      1) Administration
      2) Clinics
      3) Dialysis
      4) Emergency Room
      5) Environmental Services
      6) Laboratory
      7) Medical Staff
      8) Nursing
      9) Operating Room
     10) Radiology
     11) Research
     12) Respiratory
     13) Other

2. Implementation
   a. Based upon findings of the audit, initiate program in high volume areas. This may involve the provision or removal of containers used to collect RMW and solid waste.
      1) OR
      2) Labor and Delivery
      3) IOU
      4) Dialysis
      5) ER
      6) Other areas
   b. Education resource (e.g., poster) distribution
   c. Information distribution through facility communications network

3. Monitor program
   a. Comparison of weights before and after program’s implementation
   b. Enforce compliance
   c. Provide feedback to staff on success of program

B. Future considerations
   1. Orientation of new personnel
   2. Continuing education
   3. On-site treatment
## ANNEX 2
Commercially Available Alternative Regulated Medical Waste Treatment Technologies

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Alt. Tech.</th>
<th>Method</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annaeus Group</td>
<td>S.M.-150</td>
<td>Grinding/Steam Heat</td>
<td>up to 150 lbs./hr</td>
</tr>
<tr>
<td>10626 York Road, Suite D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hunt Valley, MD 21030</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>410-666-6160</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 410-666-6110</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.redbag.com">www.redbag.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosterile Technology, Inc.</td>
<td>Biosiris</td>
<td>Electron Beam</td>
<td>400-550 lbs/hr, 2 min. cycle</td>
</tr>
<tr>
<td>4104 Merchant Road</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fort Wayne, IN 46818</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-888-710-3792</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 219-489-3654</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e-mail: <a href="http://www.biosterile.com">www.biosterile.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circle Medical Products (Formerly Medical SafeTEC, Inc.)</td>
<td>LBF 12-5 System</td>
<td>Shredding/Chemical inactivation by sodium hypochlorite</td>
<td>800-3000 lbs/hr</td>
</tr>
<tr>
<td>3950 Culligan Avenue, Suite D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indianapolis, IN 46218</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>317-541-8080</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 317-541-0646</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMB, Ltd. Mechanical Engineering Environmental Technology &amp; Marketing</td>
<td>Sintion 1.1</td>
<td>Microwave Steam Disinfectant</td>
<td>24 tons/day (2000 lbs/hr. average)</td>
</tr>
<tr>
<td>Palbutschstrasse 115</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-8051 Graz</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Austria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>011-43-316-68 55150</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 011-43-316-68 55 10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.sintion.at">www.sintion.at</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contaminatable Container Company (Safe Sharps)</td>
<td>Safe Sharps</td>
<td>Chemical Disinfectant</td>
<td>7-23 qt. Capacity</td>
</tr>
<tr>
<td>P.O. Box 1702</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bluefield, WV 24701-1702</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>304-325-2455</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 304-325-7698</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.safesharps.com">www.safesharps.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EnviroPack Development Corporation (Acquired SPS Medical Equipment Company)</td>
<td>Needle-eater</td>
<td>Grinding/Chemical Disinfection</td>
<td>1-5 Sharps/ Grinding Cycle</td>
</tr>
<tr>
<td>224-5 Pegasus Avenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northvale, NJ 07647</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-800-978-8006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>201-784-0620</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.needleeater.com">www.needleeater.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Great Lakes Medical, LLC (Acquired Viatro Corporation)</td>
<td>Viodine</td>
<td>Liquid Sanitizer</td>
<td>500-3000 cc of liquid waste</td>
</tr>
<tr>
<td>18683 Sheldon Road</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cleveland, OH 44130</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-800-337-8243</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 216-898-5005</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Alt. Tech.</td>
<td>Method</td>
<td>Capacity</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>-----------------------------------</td>
<td>---------------------------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Isolyser Company, Inc.</td>
<td>Sharps Mgt. System</td>
<td>Solidification/Encapsulation</td>
<td>Solidifies 500-3000 cc's of fluid</td>
</tr>
<tr>
<td>4320 International Boulevard, NW</td>
<td>Liquid Treatment System - Plus and</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norcross, GA 30093</td>
<td>Orex System</td>
<td></td>
<td></td>
</tr>
<tr>
<td>770-806-9898</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 770-806-8876</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.isolyserinc.com">www.isolyserinc.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>KC Medical Waste Co., L.C.</td>
<td>KC Mediwaste</td>
<td>Hot air convection</td>
<td>20 lbs/cycle - 10 cycles/hr. or 200</td>
</tr>
<tr>
<td>4219 University Boulevard</td>
<td>Medical Waste Processor</td>
<td></td>
<td>lbs/hr.</td>
</tr>
<tr>
<td>Dallas, TX 75205</td>
<td>Model 200-A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>214-528-8900</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 214-528-0467</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MacHealthcare Services (Acquired SAS Systems, Inc.)</td>
<td>SteriMed</td>
<td>Shredding/Chemical inactivation</td>
<td>15 gallons/cycle</td>
</tr>
<tr>
<td>21 Jacobs Lane</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scotch Plains, NJ 07076</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>908-233-9369</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 908-233-8126</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M.C.M. Environmental Technologies Ltd.</td>
<td>Encore-2000 IWP</td>
<td>Shredding/Chemical inactivation</td>
<td>600 lbs/hr.</td>
</tr>
<tr>
<td>Moredet, M.P. Gilboa</td>
<td>Encore-21 00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19130 Israel</td>
<td>Encore-1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>972-6-6531104</td>
<td>IWP - 1000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 972-6-6532505</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.mcm-environment.com">www.mcm-environment.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Med Compliance Services (Successor to Mediclean Technology, Inc. Medical Compliance Services, Inc. and Kyaerner US, Inc.)</td>
<td>Needlyzer</td>
<td>Thermal-sharps needle destruction device</td>
<td>20 gauge 1.5&quot; needle oxidized in &lt;1 sec</td>
</tr>
<tr>
<td>5307 El Paso Drive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>El Paso, TX 79905</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-800-274-4627</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 915-778-8359</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Med Pro, Inc.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>817 Winchester Road, Suite 200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lexington, KY 40505</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>606-225-5375</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 606-225-5347</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.needlyzer.com">www.needlyzer.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medwaste Technologies Corp.</td>
<td>MTC Processor</td>
<td>Chemical Disinfectant</td>
<td>Up to 4,000 lb/hr</td>
</tr>
<tr>
<td>6830 North Eldridge Parkway, #110</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Houston, TX 77041</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>713-849-5480</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 713-849-9774</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.medwastetech.com">www.medwastetech.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Meteka Medizinbedarf</td>
<td>MediSter Waste Disinfection Units</td>
<td>Thermal Disinfection</td>
<td>6-60 Liter Containers/cycle</td>
</tr>
<tr>
<td>Entwicklungs-Erzeugungs-und Handelsges. m.b.H</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-8750 Judenburg, Burggasse 108</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Judenburg, Austria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>43-3572-8551-66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 43-3572-8516-66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.meteka.com">www.meteka.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Alt. Tech.</td>
<td>Method</td>
<td>Capacity</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>----------------</td>
<td>-------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>OBF Industries, Inc.</strong></td>
<td>Premicide</td>
<td>Chemical Disinfectant</td>
<td>Encapsulation of up to 2000 cc's of liquid</td>
</tr>
<tr>
<td>2719 Curtis Street</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Downers Grove, IL 60515</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-800-848-5663</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 630-515-9526</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: enviro-safe.com</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Oxidation Technologies, Inc.</strong> (Formerly part of Bio-Oxidation Services, Inc.)</td>
<td>Bio-Oxidizer</td>
<td>Electro-Pyrolysis/Oxidation</td>
<td>5-15 lbs/hr.</td>
</tr>
<tr>
<td>613 Third Street</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annapolis, MD 21403</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>410-990-9430</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 410-990-9431</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.oxid-tech.com">www.oxid-tech.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Peat, Inc.</strong></td>
<td>Plasma Arc Reactor System</td>
<td>Thermal Destruction/Pyrolysis</td>
<td>500 lbs/hr</td>
</tr>
<tr>
<td>4914 Moores Mill Road</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Huntsville, AL 35811</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>205-859-3006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 256-859-9588</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.peat.com">www.peat.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Safetec of America</strong></td>
<td>Medzam 7 Products</td>
<td>Chemical Solidification</td>
<td>Up to 1000 cc of fluid</td>
</tr>
<tr>
<td>1055 East Delavan Avenue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffalo, NY 14215</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>716-895-1822</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 716-895-2969</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.safetec.com">www.safetec.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sanitec, Inc.</strong></td>
<td>Sanitec Microwave Disinfection System</td>
<td>Shredding/Thermal inactivation by microwave</td>
<td>220-550 lbs/hr.</td>
</tr>
<tr>
<td>26 Fairfield Place</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Caldwell, NJ 07006</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>973-227-8855</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 617-942-7114</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.etven.com/sanitec/">www.etven.com/sanitec/</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stericycle, Inc.</strong></td>
<td>Stericycle Electro-Thermo Deactivation System</td>
<td>Shredding/Thermal inactivation by low frequency radio waves</td>
<td>Up to 6000 lbs/ cycle</td>
</tr>
<tr>
<td>28161 North Keith Drive</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lake Forest, IL 60045</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-800-355-8773</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 847-367-9493</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.stericycle.com">www.stericycle.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sterile Technology Industries, Inc.</strong></td>
<td>Chem-Clav</td>
<td>Shredding/Chemical/Steam heat</td>
<td>24 tons/day (average 2,000 lbs/hr.)</td>
</tr>
<tr>
<td>1155 Phoenixville Pike, Unit 105</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Park Valley Corporate Center</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>West Chester, PA 19380</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>610-436-9980</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 610-436-9986</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.stichemclave.com">www.stichemclave.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Steris Corporation</strong></td>
<td>EcoCycle 10</td>
<td>Grinding/Chemical inactivation by peracetic acid</td>
<td>2-5 lbs/10 minute cycle</td>
</tr>
<tr>
<td>5960 Heisley Road</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mentor, OH 44060</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>440-354-2600</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 440-639-4450</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.steris.com">www.steris.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Alt. Tech.</td>
<td>Method</td>
<td>Capacity</td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>Thermal Waste Technologies, Inc.</td>
<td>Demolizer System</td>
<td>Electro-thermal inactivation</td>
<td>1 qt.-1 gal. (15-20 lbs/2 hr.)</td>
</tr>
<tr>
<td>Commerce Park</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 Stoney Hill Road</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bethel, CT 06801</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>203-778-2210</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vance IDS, Inc.</td>
<td>Vance IDS System</td>
<td>Intense heat in an inert plasma atmosphere</td>
<td>350 lbs/hr.</td>
</tr>
<tr>
<td>P.O. Box 98</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pinellas Park, FL 33780</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>727-548-9572</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 727-549-8097</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.vanceids.com">www.vanceids.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vanguard Research, Inc.</td>
<td>Plasma Energy Pyrolysis System (PEPS)</td>
<td>Endothermic/Pyrolysis</td>
<td></td>
</tr>
<tr>
<td>10400 Eaton Place, Suite 450</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fairfax, VA 22030</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>703-934-6300</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 703-273-9398</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.vriffx.com">www.vriffx.com</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste Reduction by Waste Reduction, Inc.</td>
<td>WR² Tissue Digester</td>
<td>Akaline Hydrolysis</td>
<td>400 lbs/100 gallon unit</td>
</tr>
<tr>
<td>5711 West Minnesota Street</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indianapolis, IN 46241</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>317-484-4200</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax: 317-484-4201</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail: <a href="http://www.wr2.net">www.wr2.net</a></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Contains only technologies for which additional data for method, capacity, etc., could be obtained.

---

**IMPORTANT.......................... IMPORTANT............... IMPORTANT............... IMPORTANT**

A change of address notice should be sent at least six weeks in advance to the ABSA National Office to ensure that all mailings, including the journal and newsletter, will reach you. ABSA is not responsible for misrouted mail as a result of insufficient notification of an address change. Undelivered copies resulting from an insufficient address change notification will not be replaced, but single issues may be purchased at the single issue price.

**CHANGE OF ADDRESS FORM**

Name_____________________________________________________________

Old Address_________________________________________________________

Old Phone Number__________________________________________________

NEW ADDRESS_____________________________________________________

CITY________________________STATE_______ZIP + 4_____________________

NEW PHONE NUMBER_________________________________________________

E-MAIL ADDRESS___________________________________________________

Effective Date_____________________________________________________

69
A TUBERCULOSIS OUTBREAK AMONG MEDICAL WASTE WORKERS

Angela M. Weber1, Yvonne Boudreau2, and Vincent D. Mortimer3
National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention,
1Atlanta, Georgia, 2Denver, Colorado, and 3Cincinnati, Ohio

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
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\text{10} inactivation or greater of
vegetative bacteria, fungi, lipid/nonlipid viruses,
parasites, and mycobacteria, and a 4-log\text{10} reduc-
tion or greater in the concentration of viable
B. steatorhophilus 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-
culos 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-
ter 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-
culos cases in the State of Washington at that
time. In 1997, Washington State had a tuberculos
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 \textit{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 \textit{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 \textit{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 \textit{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 hazardous
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 infeed 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 speciated. 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-
cilities 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 re-used 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 3

<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>8.3</td>
<td>4.8</td>
<td>16.8</td>
<td>2.0</td>
<td>1.0</td>
<td>1.3</td>
</tr>
<tr>
<td>Inside top of in-feed chute*</td>
<td>6.3</td>
<td>7.8</td>
<td>20.4</td>
<td>2.6</td>
<td>1.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Inside top of in-feed chute</td>
<td>3.2</td>
<td>0.7</td>
<td>0.8</td>
<td>2.3</td>
<td>1.0</td>
<td>0.8</td>
</tr>
<tr>
<td>Inside top of in-feed chute</td>
<td>3.9</td>
<td>0.8</td>
<td>0.9</td>
<td>2.4</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Deep in in-feed chute</td>
<td>1.5</td>
<td>0.6</td>
<td>0.6</td>
<td>1.2</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Deep in in-feed chute</td>
<td>1.4</td>
<td>0.5</td>
<td>0.7</td>
<td>1.4</td>
<td>1.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Deep in in-feed chute</td>
<td>9.4</td>
<td>0.3</td>
<td>0.5</td>
<td>**</td>
<td>1.0</td>
<td>0.9</td>
</tr>
<tr>
<td>Inside open overhead door</td>
<td>3.6</td>
<td>0.5</td>
<td>0.6</td>
<td>0.2</td>
<td>1.0</td>
<td>0.5</td>
</tr>
<tr>
<td>Inside open overhead door</td>
<td>3.5</td>
<td>0.6</td>
<td>0.6</td>
<td>0.2</td>
<td>1.0</td>
<td>0.7</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.

** denotes data not available due to datalogger failure.
<table>
<thead>
<tr>
<th>Sample Numbers(^a) (Sampling Date)</th>
<th>Location (Sampling Time)</th>
<th>MacConkey Agar</th>
<th>Mannitol Salt Agar</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 - 6(^e) (1/27/98)</td>
<td>Press Room - In Containment (9:10)(^d)</td>
<td>Total GNR(^e) (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)</td>
<td>(S.\ aureus) (29)</td>
</tr>
<tr>
<td>76 - 78 (1/29/98)</td>
<td>Press Room - In Containment (8:14)</td>
<td>(E. coli) (102)</td>
<td>(S.\ aureus) (165)</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)(^d)</td>
<td>Total GNR (2)</td>
<td>(S.\ aureus) (16)</td>
</tr>
<tr>
<td>52 - 54 (1/28/98)</td>
<td>Pit In Containment - Between Shredders (11:15)</td>
<td>(P.\ aeruginosa) (2)</td>
<td>(S.\ aureus) (7)</td>
</tr>
<tr>
<td>79 - 81 (1/29/98)</td>
<td>Pit In Containment - Between Shredders (8:31)</td>
<td>(E. coli) (7)</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)(^r)</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)(^l)</td>
<td>(P.\ aeruginosa) (2)</td>
<td>Total Bacteria (23)</td>
</tr>
</tbody>
</table>

\(^{a}\) Sample Numbers indicate the sample set number.
\(^{b}\) CFU/m³ indicates colony-forming units per cubic meter.
\(^{c}\) GNR stands for Gram-Negative Rods.
\(^{d}\) Time of sampling.

Table 4
Air Sampling for Culturable Bacteria
Table 4
Air Sampling for Culturable Bacteria

<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>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>36 - 38 (1/28/98)</td>
<td>Vessel Re-Entry Doors (7:27)</td>
<td>Total GNR (2)</td>
<td>Total Bacteria (13)</td>
</tr>
<tr>
<td>73 - 75 (1/29/98)</td>
<td>Vessel Re-Entry Doors (6:53)</td>
<td>Total GNR (1)</td>
<td>Total Bacteria (34)</td>
</tr>
<tr>
<td>28 - 30 (1/27/98)</td>
<td>Outdoor Air - By Office Entrance (14:57)</td>
<td>No Growth</td>
<td>Total Bacteria (3)</td>
</tr>
<tr>
<td>48 - 50 (1/28/98)</td>
<td>Outdoor Air - By Office Entrance (10:16)</td>
<td>No Growth</td>
<td>No Growth</td>
</tr>
<tr>
<td>89 - 91 (1/29/98)</td>
<td>Outdoor Air - By Office Entrance (12:40)</td>
<td>No Growth</td>
<td>No Growth</td>
</tr>
</tbody>
</table>

* Concentrations are based on an average of the sample numbers listed.
* CFU/m³ = Colony forming units per cubic meter of air.
* Press operator was cleaning work area with compressed air during the collection of sample #6.
* Process was not operating during the collection of the sample due to a clog in the system.
* GNR = Gram negative rod.
* 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.
amples collected outdoors revealed the lowest concentrations (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 exhaust 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 disruption 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 observed to intermittently blow outward and a smoke tube evaluation confirmed that air inside the in-feed chute was blowing back towards the in-feed station operator. Under these circumstances, aerosolized waste could remain suspended in the plant air for an hour or more until completely removed by the general ventilation. Theoretically, over 99 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 overhead 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 prevailing winds. When the wind is from the east, exhausted 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 under 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 processing exhaust stream. In the containment room, air was found to mix well.

When tracer gas was released inside the overhead door (refer to Table 1), it was detected at the overhead door in approximately two minutes. The reappearance and time required could vary depending on the direction and speed of the prevailing winds.

Air was exhausted from the plant by the two wall fans on the north and east walls and by the process line. The two wall fans were rated at a total of 30,000 cubic feet per minute (CFM), and the primary and secondary mill negative air fans were rated at 7,000 CFM each. Since the latter fans are
in series, their air moving capacity would not be additive, so the total rated exhaust rate for the plant would be around 37,000 CFM. The air change rate calculated from decreasing tracer gas concentrations was somewhat less at 30,000 CFM. This 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 STAATT (1998). The participants of the STAATT 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 gowning 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 foggging 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


ARTHROPOD CONTAINMENT GUIDELINES UNDER DEVELOPMENT

Mark Q. Benedict
Centers for Disease Control and Prevention, NCID/DPD, Chamblee, Georgia

In response to the perceived absence of specific guidelines for laboratory containment of arthropods of public health importance, a committee has been appointed by the American Society of Tropical Medicine and Hygiene (ASTMH) to develop a document that fills this need. The document is currently in draft status, but when finalized and accepted by the ASTMH, will be recommended to NIH-CDC for inclusion in revised form in Biosafety in Microbiological and Biomedical Laboratories (BMBL). While the format is based

roughly on BMBL, the authors recognize and attempt to account for significant biological containment provided by temperate locations in which research is performed on largely tropical organisms.

The Guidelines Draft Committee welcomes comments on the document from the biosafety community. These comments can be routed to Mbenedic@cdc.gov. The most recent draft of the guidelines can be obtained at: klab.agsci.colostate.edu/~mbenedic/ACGdraftv22.pdf.

ERRATAS

The following are the correct References for the article “Human Laboratory Acquired Arbo-, Arena-, and Hantavirus Infections” by S. Ya. Gaidamovich, A. M. Butenko, and H. V. Leschinskaya which appeared on pages 5-11 of JABSA (Volume 5, Number 1, 2000).

REFERENCES


The following are the correct References for the article “Biological Contamination of the Building Environment: Sampling and Analysis” by Richard C. Fink and Elizabeth A. Gilman which appeared on pages 19-29 of JABSA (Volume 5, Number 1, 2000).

REFERENCES


83. Unpublished data from authors' studies.


ARTICLES

Cole, E. C.
Infectious Waste Disposal in Developing Countries: Recommended Minimal Practices from a Hospital Survey in Southeast Asia
Volume 5, Number 2, 2000
Pages 42-46

Gaidamovich, S. Ya., Butenko, A. M., & Leschinskaya, H. V.
Human Laboratory Acquired Arbo-, Arena-, and Hantavirus Infections
Volume 5, Number 1, 2000
Pages 5-11

Kournikakis, B., Harding, R. K., Tremblay, J. R. A., & Simpson, M.
Comparison of Protection Factors for Selected Medical, Industrial and Military Masks
Volume 5, Number 1, 2000
Pages 12-18

Morgan, D. R.
Missing the Point: A Review of Needlestick Injury and Occupational Risks from Bloodborne Viruses
Volume 5, Number 2, 2000
Pages 47-53

Salkin, I. F., Krisiunas, E., & Turnberg, W. L.
Medical and Infectious Waste Management
Volume 5, Number 2, 2000
Pages 54-69

Weber, A. M., Boudreau, Y., & Mortimer, V. D.
A Tuberculosis Outbreak Among Medical Waste Workers
Volume 5, Number 2, 2000
Pages 70-88

VIEWPOINTS

Benedict, Mark Q.
Arthropod Containment Guidelines Under Development
Volume 5, Number 2, 2000
Page 89

Fink, R. C., & Gilman, E. A.
Biological Contamination of the Building Environment: Sampling and Analysis
Volume 5, Number 1, 2000
Pages 19-29

GOVERNMENT PAPER

MMWR
Misdiagnoses of Tuberculosis Resulting from Laboratory Cross-Contamination of Mycobacterium Tuberculosis Cultures—New Jersey, 1998
Volume 5, Number 1, 2000
Pages 30-32

PRESIDENT'S PAGES

Keene, J. H.
Volume 5, Number 1, 2000
Page 3

Keene, J. H.
Volume 5, Number 2, 2000
Page 40

EDITOR'S PAGES

Knudsen, R. C.
Volume 5, Number 1, 2000
Page 4

Salkin, I. F. (Guest Editor)
Volume 5, Number 2, 2000
Page 41
ANALYSIS OF LABORATORY DESIGN

Contents include in part: Management of Biosafety; Design Issues at the Management/Facility Interface; Primary Biocontainment Devices; HVAC Issues in Secondary Biocontainment; Open BSL-2 Laboratories; Facility Guidelines for BSL-2 and BSL-3 Biological Laboratories; Design of BSL-3 Laboratories; Building a Maximum Containment Laboratory; Designing the BSL-4 Laboratory; Role of the Class III Cabinet in Achieving BSL-4; Containment Design Concepts for Extraterrestrial Sample Return; Biosafety Considerations for Design of Large Scale Facilities; Small Animal Research Facilities and Equipment; Small Animal Research Facility Management; Large Animal Research Facilities; and Waste Management Considerations.

ANALYSIS OF FACILITY DESIGN CONSIDERATIONS

Contents include in part: Working Safely with Wild Poliovirus; Biocontainment of Highly Pathogenic Avian Influenza Viruses; Maximum Containment for Researchers Exposed to Biosafety Level 4 Agents; Modular/Mobile BSL-2/3 Laboratories; Facility Maintenance Operations (Skilled Trades) for Biological Containment Laboratories; Construction and Commissioning Guidelines for Biosafety Level 4 (BSL-4) Facilities; Safety and Health Considerations for Conducting Work with Biological Toxins; Primary Containment Devices for Toxicological Research and Chemical Process Laboratories; Toxicology Laboratories; and Medical and Infectious Waste Management.

ANALYSIS OF APPLICATION OF PRINCIPLES

Contents include in part: Risk Assessment for Working with Infectious Agents in the Biological Laboratory; Biosafety Considerations in rDNA: Viral Gene Transfer Vectors, DNA-based Vaccines and Xenotransplantation; Biological Safety and the Academic Environment; Biosafety Issues in Hospital Settings; An Overview: Biological Safety from a Global Perspective; Beyond Compliance: Global Biological Safety at Johnson & Johnson; Twenty Years of Global Biosafety Programs; Ergonomic Considerations in Biomedical Research Laboratories; and Applied Safety Training in the Biomedical Facility.

ABSA/CDC 5th NATIONAL SYMPOSIUM PROCEEDINGS: RATIONAL BASIS FOR BIOCONTAINMENT

These are the papers presented during the 4-day conference jointly sponsored by ABSA and CDC from January 17-20, 1998 in Atlanta, Georgia. They provide detailed information for biological safety professionals, architects, engineers, and attorneys in the development, design, and operation of containment laboratories of all sizes. This is a must read for those involved in the operation and/or development of a containment laboratory.

<table>
<thead>
<tr>
<th>Membership Type</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member</td>
<td>$41.00</td>
</tr>
<tr>
<td>Nonmember</td>
<td>$55.00</td>
</tr>
<tr>
<td></td>
<td>$42.00</td>
</tr>
<tr>
<td></td>
<td>$57.00</td>
</tr>
<tr>
<td></td>
<td>$49.00</td>
</tr>
<tr>
<td></td>
<td>$64.00</td>
</tr>
<tr>
<td></td>
<td>$117.00</td>
</tr>
<tr>
<td></td>
<td>$162.00</td>
</tr>
<tr>
<td></td>
<td>$26.00</td>
</tr>
<tr>
<td></td>
<td>$39.00</td>
</tr>
</tbody>
</table>

Ship to:
Name ____________________________  Member: ID# ____________________________
Address ____________________________
City/State/Zip ____________________________
Total ____________________________
Check enclosed  Q  Please charge my:  QVisa  QMasterCard  QAmEx
Card # ____________________________  Exp. Date __________  Signature ____________________________

Mail or fax to: ABSA, 1202 Allanson Road, Mundelein, Illinois 60060-3808, phone 847-949-1517, fax 847-566-4580.

NOTE: Postage/handling included on all orders. Please allow 2-3 weeks for delivery.
If using a credit card, please mail or fax the form as we will need a signature on file.
GUIDELINES FOR SUBMISSIONS
Journal of the American Biological Safety Association

All submissions will be acknowledged by the ABSA National Office. The Journal of the American Biological Safety Association (JABSA) uses a blind peer review procedure for articles, brief reports, and viewpoints. Final decisions regarding publication are made by the reviewers, Editor, and Associate Editor. The following are the guidelines for submissions. Submissions that do not conform to these guidelines will be returned to the author without review.

SUBMISSION CATEGORIES
Articles—Full-length articles may focus on the theory, practice, and research in biological safety or related areas. Articles must include an abstract of approximately 100-150 words summarizing the major point of the article.

Brief Reports—Short articles which focus on the results of research are appropriate for this section. Brief reports should include information on the research design, methods, and results. An abstract of approximately 100-150 words must also be included.

Viewpoints—Short articles focusing on personal experiences may be submitted to this section.

Book Reviews—Reviews of books of interest to biological safety may be submitted at any time. Books which authors wish to have considered for review may be sent directly to the ABSA National Office.

Video Reviews—Reviews of media (videos) may be submitted at any time. Media which producers wish to have considered for review may be sent directly to the ABSA National Office.

Commentaries—Brief comments on submissions published in JABSA, issues critical to the profession and practice of biological safety, or letters to the Editor may be submitted to this section and should conform to the style of all other submissions.

OTHER REQUIREMENTS
1. Send five (5) typeset copies of each submission to: Editor, Journal of the American Biological Safety Association, c/o American Biological Safety Association, 1202 Allanson Road, Mundelein, IL 60060-3808, U.S.A. Neither ABSA nor the Editor can be responsible for submissions sent to any other address. Only original submissions that are not under consideration by another periodical or publisher are acceptable.

2. Submissions should be typeset on 8-1/2" x 11" paper using 1" margins, single-spacing, and full-justification. Indent paragraphs five (5) spaces. References, footnotes, table captions, and quotations should be single-spaced as well. Acceptable fonts are Times New Roman, Arial, AvantGarde, Helvetica, and Universal in 12 point. Avoid dot matrix printing. Primary headings should be flush left, bolded, and capitalized throughout the submission. Secondary headings should be flush left, bolded, and have the first letter of all main words capitalized.

3. An abstract of 100-150 words must be included with full-length articles and brief reports.

4. Abbreviations of journal titles and style of reference lists will follow the American Society for Microbiology's ASM Style Manual for Journals and Books. ASM journals use the alphabet-number system for references. All works cited are numbered alphabetically by author's name and placed in a section headed "References" at the end of the text.

5. A cover sheet should be prepared to include the full name(s) and degree(s) of the author(s), professional affiliations, and the return mailing address of the author to whom correspondence can be sent. Authors' names, positions, titles, and places of employment should not appear in the body of the paper to assure anonymity and to facilitate the blind review process.

6. Use tables sparingly and typeset them on separate pages. All tables, charts, or diagrams must be computer-generated or professional, quality, original drawings which are legible, able to withstand reduction, and submitted as camera ready artwork. Typeset in a vertical (portrait) format on separate pages, including any legend, label, or number associated with them. Refer to each as Table 1, Table 2, etc., centered above the table. Captions should be single-spaced. Tables, etc., should not be included in the electronic copy on diskette; however, there should be a notation of where they are to be inserted throughout the submission. Include the originals and five (5) photocopies of each with the submission.

7. Photographs must be at least 3-1/2" x 5" and black and white prints, preferably with high contrast. Photocopies of illustrations are not acceptable for publication. Figure numbers, captions, orientation, and the author's name should be noted on the back of each original photograph. Captions must be typed and submitted on a separate sheet of paper as well. Please refer to figures in the text as Figure 1, Figure 2, etc. There should be a notation of where the photographs are to be inserted throughout the submission. Include the original figures and five (5) photocopies of each with the submission.

8. Lengthy quotations (300 words or more from one source) require written permission from the original copyright holder for reproduction. Adaptation of tables or figures from copyrighted sources also requires approval. It is the author's responsibility to secure such permissions. A copy of the copyright holder's written permission must be provided to the Editor immediately upon acceptance of the submission for publication. The author(s) bear full responsibility for the accuracy of all references, quotations, and materials accompanying their submissions.

9. It is expected that any submission accepted for publication in JABSA will go through at least one (1) revision before publication. Authors must include their submission on diskette (electronic copy) along with their five (5) typeset copies. The diskette should be prepared on either an IBM or IBM-compatible computer. The submission should be formatted using one of the following programs: Microsoft Word, Microsoft Publisher, or WordPerfect. ASCII files are also acceptable.
ATTENTION AUTHORS

Please complete the following information and include with your submission.

Name

Degrees/Credentials

Address

Phone Numbers
Home  Work

Type of Submission (check one):

☐ Article  ☐ Brief Report  ☐ Viewpoint
  ☐ Book Review  ☐ Video Review  ☐ Commentary

Title of Submission

CHECKLIST

☐ Five (5) copies, typeset on 8-1/2" x 11" with 1" margins.

☐ Original tables, figures, and/or illustrations and five (5) photocopies of each.

☐ Paper and references adhere to American Society for Microbiology's ASM Style Manual for Journals and Books.

☐ Abstract of 100-150 words (for articles and brief reports only).

☐ Detachable cover sheet with author's full name(s), degree(s), professional affiliations, and credentials.

☐ This Attention Authors form.

Author's Signature  Date

Please send completed form with submission to: Editor, Journal of the American Biological Safety Association, 1202 Allanson Road, Mundelein, IL 60060-3808, U.S.A.