Advertising Rates

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Color rates: $350 for first color (after black) and $300 each additional color. 15% discount for agencies (orders must be supplied on agency letterhead).

Mechanical Requirements

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Trim size—8-1/2" × 11"
Film—133 line screen, right reading, emulsion side down, color separated

Submission Deadlines

| February 1 for Spring issue | August 1 for Fall issue | May 1 for Summer issue | November 1 for Winter issue |

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S. Mark Allen

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A Critical Review
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(Organizational and Controlling, Medical, and Sanitary—Antiepidemiological Aspects)
Evgeniy A. Stavskiy, Barbara Johnson, Robert J. Hawley, Jonathan T. Crane,
Nikolay B. Cherny, Irina V. Renau, and Sergey V. Netesov

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Revisions to the National Sanitation Foundation International/American National
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David S. Phillips

Capsule
Ed Kristunas

Ask the Experts—Biosafety Requirements for Human Cell Lines
John H. Keene

Biosafety Tips
Karen B. Byers
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**Guidelines for Submissions**

**Attention Authors**

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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.

About the Cover

A Class II B2 Biological Safety Cabinet for which the National Sanitation Foundation International/American National Standards Institute recently published revised field certification standards as described by David Phillips in this issue’s Special Features Section.
Through the efforts of the membership over this past year, ABSA has built upon and further developed its reputation as a national and international source of expertise in biosafety and biosecurity. As President, it has been rewarding to see an increase in our participation in providing guidance to national and international policymakers in the areas of hazardous goods transportation, biosecurity, polio vaccine and eradication, biosafety (ABSA now provides extensive support to OSHA), and numerous other areas. Commensurate with our Mission Statement, many of these achievements are a result of the publication of position papers, training courses, outreach to other professional organizations, communication via our web site and journal, and the networking efforts of our membership.

The ABSA 40-hour course offered in June, Fundamentals of Biosafety, was a tremendous success. The information provided on logistics management was top quality. The Council and I congratulate LouAnn Burnett and Anne-Marie Bakker of the Training and Education (T&E) Committee, the lecturers, and especially all the ABSA members who volunteered their time and effort in developing the course curriculum and material. As if this were not enough of a challenge, the T&E Committee worked closely with our robust and proactive affiliate Biological Safety Affairs Forum (BSAF) and hosted a highly successful and well-attended ABSA Summer Seminar Series program. I applaud T&E and BSAF for their initiative and coordinated efforts to offer the BSAF membership a great, locally-based training opportunity. This is another novel way ABSA can help support its affiliates, and we look forward to expanding and supporting other affiliates next year.

The Scientific Program Committee, chaired by Karen Byers, has developed an outstanding program for our 2003 Annual Conference, which can be viewed on the ABSA web site. This year T&E will offer 22 preconference and postconference courses to accommodate individuals of all skill- and knowledge-levels in biosafety and biosecurity, as well as offer the CBSP Review Course. The National Registry of Microbiologists (NRM) Certified Biological Safety Professional (CBSP) exam date will be announced shortly on the ABSA web site. This year’s program is timely and very diversified, with a wealth of original papers and round tables. The Local Arrangements Committee, chaired by Harriet Izenberg, has worked with the SPC to recruit expert speakers on SARS and other topics of interest to the membership. They have also arranged for our closing banquet at the Franklin Institute, a real showstopper. The Philly Local Arrangements Committee (LAC) will be available to provide information on local sites, entertainment, and restaurants. My sincere thanks to Karen, the SPC, Harriet, and the LAC for their hard work and efforts to recruit high-quality presenters and develop a social agenda that will make this a memorable conference. I would also like to thank and acknowledge this year’s sponsors: Novartis, Tier DE, Baker Company, ENV Services, Merck, Aventis, Pfizer, and P&K Microbiology Services, for their generous contributions and support.

Earlier this summer ABSA received an invitation from the United Nations Secretariat for the Biological Toxins and Weapons Convention (BTWC) to develop a position paper on Biosecurity and the BTWC, as well as discuss ABSA’s position and elements of biosecurity with BTWC delegates and experts in Geneva in August. The paper submitted to Chairman, Ambassador Tibor Toth is included in
this issue of Applied Biosafety.

In the last issue of Applied Biosafety, we were treated to a comprehensive paper on the status and evolution of UN Transportation of Hazardous Goods Regulations. Mary Cipriano, our representative, has provided a consistently high level of technical “value added” in this arena, and has been invited by CDC to participate in their meeting, “Infectious Substances Transport by Air After January 2005—discussion on 13th edition of UN Model Regulations” as the ABSA expert. My thanks again to Mary for sharing her technical acumen on behalf of ABSA.

Mark your calendars for the next Biosecurity Conference in Atlanta in January 2004. The conference is offered in partnership with CDC and ABSA.

As part of the Scientific Steering Committee, I have no doubts it will be timely and informative, and provide applied as well as overarching perspectives on the evolution of biosecurity.

I urge all members who have an opinion of Applied Biosafety to attend the Membership Meeting. I will be providing an update on the status of the journal, challenges we have faced through the year, restructuring actions, and potential issues and solutions.

It has been an honor to serve as President over the past year. As an organization we have made many wonderful and important contributions to biosafety and biosecurity. I thank the membership for this opportunity and wish Stefan Wagener the best and success as our new President.

---

Join a Committee

Have you ever considered joining a committee? When you choose to serve on a volunteer committee, you open up a world of possibilities for networking, professional growth, and career opportunities while serving your profession. Volunteer member groups are the backbone of the association because they:

- Serve as a forum for exchange of information
- Advance the science in all specialties of biosafety
- Develop guidelines and standards
- Provide education and training
- Link ABSA to many other institutions

You should explore committees in areas of the profession where you are active or have an interest. There is a great variety; you can be sure to find one of interest to you. Please review the list of committees and identify those areas in which you would like to participate or contact the chair of the committee (http://www.absa.org/abocommittees.html) that interests you to find out more information about the committee’s goals. You are also invited to attend the committee’s meeting during our national conference or at any other time (all committee meetings are open).

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Errata

Steven Kridel, RBP, was inadvertently left off the RBP list in the 2003 ABSA Directory. Please include Mr. Kridel’s name in your copy. We apologize for any inconvenience.
Overview of Biomedical Waste Technology of Contaminants in Letters

S. Mark Allen
Allen Engineering and Sciences, P.C., Orchard Park, New York

Abstract

Nonincineration methodologies for proper treatment of biomedical waste are in increasing demand around the world, as more and more countries adopt regulations restricting air pollution.

Allen Engineering & Sciences, P.C., recently prepared a report ("Biomedical Waste Treatment and Disposal Options in the Philippines," May 2002) regarding biomedical waste treatment technologies and vendors, at the request of the Philippine Environmental Management Bureau (EMB). Data for the Report were developed under a grant to EMB from the United States Trade and Development Agency.

The Report is intended to provide information needed by EMB and potential buyers of nonincineration biomedical waste treatment equipment for use in the Philippines, and to facilitate communication among vendors of such equipment and potential buyers in that country. It also provides useful information for other parties and governments around the world that are interested in gathering information on current technologies for biomedical waste treatment. Over 50 vendors of biomedical waste treatment technology and equipment were contacted, as part of the Report research effort. This paper summarizes information developed for the Report.

The following are salient points that have grown out of the research conducted for the Report.

1. The limited budgets and size (bed count) of most Philippine medical facilities will probably inhibit the purchase of new, in-house biomedical waste treatment equipment for many of these facilities. Low-technology approaches to sharps (e.g., filling partially full used sharps containers with cement mortar before disposing of them) should be considered, at least for small or remote hospitals.

2. Secure landfills are not available in the Philippines. Solid waste, including treated biomedical waste, is subject to scavenging at open dumpsites. Adequate treatment and destruction of biomedical waste, particularly sharps (e.g., used hypodermic needles), is therefore a significant concern.

3. Notwithstanding the generally limited budgets noted above, a significant market for nonincineration biomedical waste treatment equipment and services exists in the Philippines.

Description of Purpose

General

The Philippine Clean Air Act of 1999 and its November 2000 Implementing Rules and Regulations require that all incineration of biomedical wastes be phased out by July 17, 2003. EMB is charged with enforcing this requirement. EMB has requested investigation of technologies that would comply with the Clean Air Act, while providing the necessary destruction of pathogens in such wastes. This paper summarizes the following key elements of the Report written to address that request:

• A listing of technology types and vendors
• An indication of approximate capital costs for treatment systems
• A tabulation of vendor pathogen destruction performance claims
In the Philippines, “biomedical waste” refers to pathological wastes, pharmaceutical wastes, chemical wastes, and sharps defined as follows (Philippines Republic Act No. 8749):

“Pathological wastes” include all human tissue (whether infected or not) such as limbs, organs, fetuses and body fluid; animal carcasses and tissue, together with all related swabs and dressings;

“Pharmaceutical wastes” include pharmaceutical products; drugs and chemicals that have been returned from wards; have been spilled or soiled; are expired or contaminated; or are to be discard for any reason;

“Chemical wastes” include discarded solid, liquid or gaseous chemicals from laboratories or other sources such as diagnostic work, environmental work, cleaning, housekeeping and disinfecting procedures; (and)

“Sharps” include needles, syringes, scalpels, blades and any other items that could cut or puncture.

The wastes listed above are generally referred to as “biomedical waste” or “regulated medical waste.”

The Report is considered a necessary step in order to perform the following tasks:

• Verify the feasibility of the Clean Air Act-mandated phasing out of biomedical waste incineration.
• Provide technical and cost information regarding available alternative technologies.
• Achieve regulatory acceptance for widespread use of appropriate alternative biomedical waste treatment and disposal technologies in the Philippines, by providing a source of information that regulators can use in order to evaluate treatment system proposals for compliance with the existing Philippine regulations.

The Report was developed with the cooperation of the EMB and the Philippine Department of Health (DOH). The Report is not intended as a guide for the handling and management of biomedical waste, which in itself is a large and significant topic. It should be noted, however, that such waste should be properly segregated and handled as part of an overall waste management strategy. Proper waste segregation and management are keys to minimizing the amount of waste that must ultimately be treated and disposed of, as much waste originating in medical facilities (e.g., cafeteria waste, general waste) may be disposed of without treatment if it is properly segregated from biomedical waste.

**Importance of Treatment Technology Guidance**

Financial and operational issues (including utility requirements such as steam) are important in the selection of capital equipment such as biomedical waste treatment systems. In addition, there are several factors that should enter into the selection of biomedical waste treatment technology. These include:

1. Need to comply with Clean Air Act requirements (thus avoiding harmful emissions of air pollutants)
2. Need to prevent possible improper disposal of untreated biomedical waste in landfills (when landfills become available), in open dumps, or by release to informal recyclers/scavengers
3. Need to properly disinfect waste to prevent possible transmission of disease (This is especially important because virtually all wastes are subject to scavenging in the Philippines.)
4. Potential need to properly treat the newly discovered, difficult-to-treat infectious protein particle (prion) that causes Creutzfeldt-Jacob Disease (CJD) or variant Creutzfeldt-Jacob Disease (vCJD).

It should be noted that the biomedical waste treatment performance levels provided in Table 1 (for which vendor pathogen destruction claims are provided in Table 3) do not address destruction of prions. Treatment of prions as such is beyond the scope of the present article. For facilities that anticipate a need to treat prion-containing waste, prion-specific performance information should be sought from the vendor and verified by appropriate testing agencies.

**Biomedical Waste Treatment Performance**

Performance indicators/levels of biomedical waste treatment (degrees of microbial inactivation or “disinfection levels”) are listed in Table 1. Table 1 is
Table 1
Biomedical Waste Treatment Performance Requirements

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<th>Level</th>
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<tr>
<td>I</td>
<td>6 log 10 Inactivation of vegetative bacteria and fungi</td>
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<tr>
<td>II</td>
<td>6 log 10 Inactivation of mycobacteria</td>
</tr>
<tr>
<td>III</td>
<td>4 log 10 Inactivation of <em>B. subtilis</em> (heat) or <em>B. stearothermophilus</em> (chemical)</td>
</tr>
<tr>
<td>IV</td>
<td>6 log 10 Inactivation of <em>B. stearothermophilus</em></td>
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derived from “Guidance for Evaluating Medical Waste Technologies” (Jan. 1993; EPA contract no. 68-WO-0032). Microbial inactivation refers to the effects of physical or chemical processes that render microorganisms incapable of multiplication. Such processes may either kill the organisms or injure them to the extent that effective repair and subsequent growth are not possible. Level IV is the most stringent level of microbial inactivation.

Vendor Information Tables

Table 2 (presented on the following pages) presents contact information for 47 vendors of biomedical waste treatment technologies, located in seven countries. Table 3 provides a comparison of treatment system technologies, including performance and other data, for systems provided by the 21 vendors that responded to requests for information for the Report. Table 2 groups thermal processes into three groups: low heat, medium heat, and high heat. Low heat thermal treatment involves achievement of temperatures approximating the boiling point of water (e.g., use of microwaves or steam autoclaving) or somewhat higher temperatures for pressurized steam systems. Medium heat treatment takes place above 350°F and below 700°F. Finally, high heat thermal treatments operate at more elevated temperatures, generally ranging from around 1,000°F (540°C) to 15,000°F (8,300°C) or higher. High heat processes involve chemical and physical changes resulting in destruction of the waste.

The reader should note that the data (including claims of pathogen destruction) were provided by the companies that produce the treatment technologies. Each vendor was requested to provide written verification of its system’s claimed pathogen destruction capability. A letter from a State regulatory authority indicating that the system will “totally destroy all pathogens which have any potential to be harmful to health and the environment” or a sterilization assay report showing laboratory test results for destruction of *B. stearothermophilus*, are examples of such verification. The following vendors provided such written verification:

- Environmental Waste International
- Hydroclave Systems Corp.
- Matrix Technology PTY Ltd.
- San-I-Pak
- Sterile Technology
- Thermal Waste Technologies, Inc.
- Vanguard Research, Inc.

Allen Engineering & Sciences, P.C. makes no claim (either in support or to the contrary) regarding the information provided by vendors as presented in this article.

Information on Tables

Type Key: H = high heat thermal; M = medium heat; L = low heat; I = irradiation; C = chemical/mechanical; O = other; U = undefined

Notes:
1. Please refer to Table 1 regarding Disinfection Levels. Asterisk (*) denotes likely technology-based disinfection level, but confirmation testing has not been performed.
2. Each vendor was requested to provide written verification of its system’s claimed pathogen destruction capability. A letter from a State regulatory au-
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<td>C</td>
<td>Waste Reduction by Waste Reduction, Inc.</td>
<td>5711 West Minnesota Street</td>
<td>46241-3825</td>
<td>317-484-4200 or 877-749-2783</td>
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<td>L</td>
<td>BondTech Corp.</td>
<td>2400 North Highway 27</td>
<td>42503-5548</td>
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<td>L</td>
<td>Mark-Costello Co.</td>
<td>1145 East Dominguez Street</td>
<td>90746-3566</td>
<td>310-637-1851</td>
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<td>125 James Way</td>
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<td>Chemical</td>
<td>C</td>
<td>Matrix Technology PTY Ltd.</td>
<td>P.O. Box 1213</td>
<td>4870</td>
<td>+61 7 4051 2955</td>
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<td>Chemical/Mechanical</td>
<td>C</td>
<td>DiMino</td>
<td>Enviropack Development Corp.</td>
<td>Northvale NJ</td>
<td>800-978-8006 or 201-767-6040</td>
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<tr>
<td>Dry Heat Treatment</td>
<td>H</td>
<td>Thermal Waste Technologies, Inc.</td>
<td>19 Stony Hill Road, Suite 4</td>
<td>06801-1051</td>
<td>888-336-6549 or 203-778-2210</td>
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<td>Dry Inorganic Chemical-Shredding</td>
<td>C</td>
<td>Palmer</td>
<td>Positive Impact Waste Solutions, Inc.</td>
<td>5030 East University Boulevard</td>
<td>Odessa TX 79762</td>
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<td>Biomedical Disposal, Inc. (SharpX)</td>
<td>3690 Holcomb Bridge Road</td>
<td>Norcross GA 30092-2727</td>
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Type Key: H = high heat thermal; M = med. heat; L = low heat; I = irradiation; C = chemical/mechanical; O = other; U = undefined
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<td>403 Ken Mar Industrial Parkway OH 44147-2956 USA 877-797-4277 or 440-717-9860</td>
<td><a href="mailto:jadkins@safeguardsmd.com">jadkins@safeguardsmd.com</a></td>
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<td>Electrocatlytic Wet Oxidation</td>
<td>C</td>
<td>Rogers</td>
<td>Delphi Research, Inc.</td>
<td>701 Haines Avenue NW Albuquerque NM 87102-1227 USA 505-292-9315</td>
<td><a href="mailto:trogers@delphi-res.com">trogers@delphi-res.com</a></td>
</tr>
<tr>
<td>Electron Beam</td>
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<td>Wilson</td>
<td>Bio-Sterile Technology, Inc.</td>
<td>4104 Merchant Road Ft. Wayne IN 46818-1248 USA 888-710-3792</td>
<td><a href="mailto:rwilson10@nc.rr.com">rwilson10@nc.rr.com</a></td>
</tr>
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<td>Tomasello</td>
<td>Stericycle Inc.</td>
<td>28161 North Keith Drive Lake Forest IL 60045-4528 USA 847-607-2053</td>
<td><a href="mailto:ttomasello@stericycle.com">ttomasello@stericycle.com</a></td>
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<td>Gillette</td>
<td>Medical Disposal, Inc.</td>
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<td>Thermoselect</td>
<td>Via Naviglio Vecchio 4 Locarno CH 6600 Switzerland 4191-756-2525</td>
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<td>Liquids Treatment System</td>
<td>U</td>
<td>Furlow</td>
<td>Microtek Medical, Inc. (Isolyser)</td>
<td>4320 International Boulevard NW Norcross GA 30093-3228 USA 800-844-0988</td>
<td><a href="mailto:jatwood@orex.com">jatwood@orex.com</a></td>
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<td>L</td>
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<td>CMB Maschinenbau und Handels GmbH</td>
<td>Plabutschenerstrasse 115, A-8051 Graz Austria (43-316) 68-55-150</td>
<td><a href="mailto:cmb@sinton.at">cmb@sinton.at</a></td>
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<td>Needle/sharp destruction</td>
<td>O</td>
<td>Walter</td>
<td>MedPro, Inc.</td>
<td>817 Winchester Road, Suite 200 Lexington KY 40505-3744 USA 859-225-5375 x102</td>
<td><a href="mailto:wweller@needlyzer.com">wweller@needlyzer.com</a></td>
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<td>Bailey</td>
<td>Safesharps</td>
<td>P.O. Box 1702 Bluefield WV 24701-1702 USA 304-325-2455 x10</td>
<td><a href="mailto:jbailey@safesharps.com">jbailey@safesharps.com</a></td>
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<td>Rodgers</td>
<td>Earth-Shield Company</td>
<td>304 Yampa Street Bakersfield CA 93307-2722 USA 661-322-0300</td>
<td><a href="mailto:mrogers@earth-shield.com">mrogers@earth-shield.com</a></td>
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<td>Peracetic Acid-Grinding</td>
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<td>Steris Corp. (Ecocycle)</td>
<td>5960 Heisley Road Mentor OH 44060-1834 USA 800-989-7575 x27012 or 440-354-2600</td>
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<tr>
<td>Plasma Pyrolysis</td>
<td>H</td>
<td>James T. Woo</td>
<td>Plasma Pyrolysis Systems</td>
<td>P.O. Box 158 Stuyvesant Falls NY 12174-0158 USA 518-828-4684</td>
<td><a href="mailto:wojjt@interscience.com">wojjt@interscience.com</a></td>
</tr>
<tr>
<td>Plasma Pyrolysis</td>
<td>H</td>
<td>Art Yando</td>
<td>Vanguard Research Inc.</td>
<td>8384-C Terminal Road Lorton VA 22079-1422 USA 703-339-6222</td>
<td><a href="mailto:ayando@vripeco.com">ayando@vripeco.com</a></td>
</tr>
</tbody>
</table>
Table 2 (Continued)
Biomedical Waste Treatment Technology Vendors

<table>
<thead>
<tr>
<th>Description/Type</th>
<th>Contact</th>
<th>Agency</th>
<th>Address</th>
<th>Telephone</th>
<th>E-mail address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma Pyrolysis</td>
<td>H Dr. Kenneth</td>
<td>Wittle Electro-Pyrolysis, Inc.</td>
<td>996 Old Eagle School Road</td>
<td>610-687-9070</td>
<td><a href="mailto:kwittle@electropyrolysis.com">kwittle@electropyrolysis.com</a></td>
</tr>
<tr>
<td></td>
<td>H Mr. Omar</td>
<td>Castellon Peat International</td>
<td>7529 S Memorial Parkway</td>
<td>256-883-8997</td>
<td><a href="mailto:omar.castellon@peat.com">omar.castellon@peat.com</a></td>
</tr>
<tr>
<td></td>
<td>H</td>
<td>Daystar Technologies/</td>
<td>Nibancho-on Bldg 47 11-6,</td>
<td>81-3-5275-2411</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Prometron Technics Corp.</td>
<td>Nibancho, Chiyoda-ku</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H Mr. Murray</td>
<td>Vance Bio Arc, Inc.</td>
<td>P.O. Box 98</td>
<td>727-548-9572</td>
<td><a href="mailto:info@arctechnologiesgroup.com">info@arctechnologiesgroup.com</a></td>
</tr>
<tr>
<td></td>
<td>H Mr. Joseph</td>
<td>Klimmek Startech Environmental</td>
<td>79 Old Ridgefield Road</td>
<td>203-762-2499</td>
<td><a href="mailto:jklimmek@starcht.net">jklimmek@starcht.net</a></td>
</tr>
<tr>
<td></td>
<td>H Mr. Serge</td>
<td>Randhava Unitel Technologies</td>
<td>411 Business Center Drive</td>
<td>847-297-2265</td>
<td><a href="mailto:unitelone@aol.com">unitelone@aol.com</a></td>
</tr>
<tr>
<td></td>
<td>H Mr. Jeffrey E. Surma Integrated Environmental Technologies LLC</td>
<td>1935 Butler Loop</td>
<td>Richland WA 99352 USA 509-946-5700</td>
<td><a href="mailto:jesurma@inentec.com">jesurma@inentec.com</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H Mr. Jason</td>
<td>McClafferty MSE Technology</td>
<td>P.O. Box 4078</td>
<td>406-494-7100</td>
<td><a href="mailto:jmccafferty@mse-ta.com">jmccafferty@mse-ta.com</a></td>
</tr>
<tr>
<td>Pre-Shredding/ Steam-Mixing</td>
<td>L Ms. April Jorgensen Aegis Bio-Systems LLC</td>
<td>2500 S Broadway Suite 200</td>
<td>Edmond OK 73013 USA 405-341-4667</td>
<td><a href="mailto:ajorgensen@aegis.com">ajorgensen@aegis.com</a></td>
<td></td>
</tr>
<tr>
<td>Reverse</td>
<td>M Mr. Michael Vocilka Environmental Waste Int'l.</td>
<td>283 Station Street</td>
<td>Ajax ON L1S 153 Canada 905-686-8689</td>
<td><a href="mailto:mjcvoilka@ewmc.com">mjcvoilka@ewmc.com</a></td>
<td></td>
</tr>
<tr>
<td>Polymerization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Needle/sharps</td>
<td>O Mr. Gary</td>
<td>Burdette Imagination Medical, Inc.</td>
<td>12855 Phillips Highway</td>
<td>904-268-5531</td>
<td><a href="mailto:grburdette@aol.com">grburdette@aol.com</a></td>
</tr>
<tr>
<td>destruction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shredding/</td>
<td>L Mr. Bill</td>
<td>Jones Sterile Technology</td>
<td>5725 West Minnesota Street</td>
<td>317-484-4200</td>
<td><a href="mailto:chemclay@aol.com">chemclay@aol.com</a></td>
</tr>
<tr>
<td>Steam-Mixing/</td>
<td></td>
<td>Industries, Inc. (STI) subsidiary of WR^2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drying, Chemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description/Type</td>
<td>Contact</td>
<td>Agency</td>
<td>Address</td>
<td>Telephone</td>
<td>E-mail address</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>----------</td>
<td>-------------------------------</td>
<td>--------------------------------</td>
<td>-----------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Shredding-Mixing (“Sterimed”)</td>
<td>C Mr. Meier Wais</td>
<td>MCM Environmental Technologies</td>
<td>Moledet, M.P.</td>
<td>19130</td>
<td>Israel</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Gilboa</td>
<td>972-6-653-1104</td>
<td><a href="mailto:mcm@kinneret.com.il">mcm@kinneret.com.il</a></td>
</tr>
<tr>
<td>Shredding-Steaming-Mixing/Drying</td>
<td>L Mr. Mike Neubauer</td>
<td>Ecolotec, LLC</td>
<td>8 Savannah Circle</td>
<td>35175-7822</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Union Grove AL</td>
<td>256-498-1114</td>
<td><a href="mailto:tmiken@mindspring.com">tmiken@mindspring.com</a></td>
</tr>
<tr>
<td>Sodium Hypochlorite-Hammermill</td>
<td>C Mr. Jon Watson</td>
<td>Circle Medical Products, Inc.</td>
<td>3950 Culligan Avenue, #D</td>
<td>46218-5509</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Indianapolis IN</td>
<td>317-541-8080</td>
<td><a href="mailto:cirlclemed@netdirect.net">cirlclemed@netdirect.net</a></td>
</tr>
<tr>
<td>Sodium Hypochlorite-Shredding (mobile)</td>
<td>C Mr. Raymond Hart</td>
<td>Med-Shred</td>
<td>5855 Westheimer</td>
<td>77057</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Houston TX</td>
<td>713-818-2387</td>
<td></td>
</tr>
<tr>
<td>Specialized cement manufacturing</td>
<td>H Mr. Mike Mensinger</td>
<td>GTI</td>
<td>1700 South Mount Prospect Road</td>
<td>60018-1804</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Des Plaines IL</td>
<td>847-768-0602</td>
<td><a href="mailto:mike.mensinger@gastechnology.org">mike.mensinger@gastechnology.org</a></td>
</tr>
<tr>
<td>Steam-Mixing-Fragmenting/Drying</td>
<td>L Ms. Rebecca Fawcett</td>
<td>Hydroclave Systems Corp.</td>
<td>672 Norris Court</td>
<td>K7P 209</td>
<td>Canada</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Kingston ON</td>
<td>613-389-8373</td>
<td><a href="mailto:inquire@hydroclave.com">inquire@hydroclave.com</a></td>
</tr>
<tr>
<td>Steam-Mixing-Fragmenting/Drying/Shredding</td>
<td>L Ms. Sharon Schudmak</td>
<td>Tempico, Inc.</td>
<td>P.O. Box 428</td>
<td>70447-0428</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Madisonville LA</td>
<td>504-845-0800 or 800-728-9006</td>
<td><a href="mailto:sschudmak@tempico.com">sschudmak@tempico.com</a></td>
</tr>
<tr>
<td>Thermal Depolymerisation</td>
<td>M Mr. Brian Appel</td>
<td>Changing World Technologies</td>
<td>460 Hempstead Avenue</td>
<td>11552-2716</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>West Hempstead NY</td>
<td>516-486-0100</td>
<td><a href="mailto:cwt@changingworldtech.com">cwt@changingworldtech.com</a></td>
</tr>
<tr>
<td>Thermal Depolymerization</td>
<td>M Mr. Ed Krisiunas</td>
<td>Sharps Compliance, Inc. (agent for Changing World Technologies)</td>
<td>Burlington CT</td>
<td>USA</td>
<td><a href="mailto:ekrisiunas@aol.com">ekrisiunas@aol.com</a></td>
</tr>
<tr>
<td>Thermal Destruction</td>
<td>H Mr. Dean Robbins</td>
<td>Therm-Tec Inc.</td>
<td>20525 Southwest Circle Road</td>
<td>97140-8339</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sherwood OR</td>
<td>503-625-7575</td>
<td><a href="mailto:thermtc@aol.com">thermtc@aol.com</a></td>
</tr>
<tr>
<td>Vacuum-Steaming-Compaction</td>
<td>L Mr. Arthur McCoy</td>
<td>San-I-Pak</td>
<td>P.O. Box 1183</td>
<td>95378-1183</td>
<td>USA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Tracy CA</td>
<td>209-836-2310</td>
<td><a href="mailto:arthurmcc@aol.com">arthurmcc@aol.com</a></td>
</tr>
</tbody>
</table>
## Table 3
Comparison of Biomedical Waste Treatment Technologies

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Description</th>
<th>Type</th>
<th>Capital Cost</th>
<th>Feed Prep</th>
<th>Energy</th>
<th>Capacity/Process Flow lb/</th>
<th>Env. Control Measures</th>
<th>Waste Unrecognizable</th>
<th>Waste Vol. Reduce, %</th>
<th>Disinfection Level*</th>
<th>Disinfection Level Verification*</th>
<th>Advantages (see below)</th>
<th>Disadvantages (see below)</th>
<th>Training</th>
<th>Limitations*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BondTech Corp.</td>
<td>Autoclave or Retort</td>
<td>L</td>
<td>$210,000</td>
<td>Shredder (included)</td>
<td>240 kW boiler 561</td>
<td>Closed system</td>
<td>Y</td>
<td>85%</td>
<td>IV</td>
<td>No</td>
<td>A1, A3</td>
<td>D3</td>
<td>Classroom</td>
<td>Not specified</td>
<td></td>
</tr>
<tr>
<td>Changing World Technologies</td>
<td>Thermal Depolymerization</td>
<td>M</td>
<td>Not provided</td>
<td>Shredder (included)</td>
<td>220 A</td>
<td>Closed system</td>
<td>Y</td>
<td>90%</td>
<td>IV</td>
<td>No</td>
<td>A1</td>
<td>D2, D3</td>
<td>1 wk</td>
<td>None listed</td>
<td></td>
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<tr>
<td>Circle Medical Products, Inc.</td>
<td>Sodium Hypochlorite-Hammermill</td>
<td>C</td>
<td>$295,000</td>
<td>Grinder (included)</td>
<td>400 V</td>
<td>500-2000 HEPA filters</td>
<td>Y</td>
<td>90%</td>
<td>IV</td>
<td>No</td>
<td>A1, A3</td>
<td>D3, D5</td>
<td>2 days</td>
<td>None listed</td>
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<tr>
<td>Electro-Pyrolysis, Inc.</td>
<td>Plasma Pyrolysis</td>
<td>H</td>
<td>$1MM to $10 MM</td>
<td>Not required</td>
<td>.75 kwh/lb feed</td>
<td>100-3000 APC system</td>
<td>Y</td>
<td>90%</td>
<td>IV*</td>
<td>No</td>
<td>A1</td>
<td>D1, D2</td>
<td>1 wk</td>
<td>None listed</td>
<td></td>
</tr>
<tr>
<td>Environmental Waste International</td>
<td>Reverse Polymerization</td>
<td>M</td>
<td>$1,100,000</td>
<td>Grinder (included)</td>
<td>Nat. gas, elect.</td>
<td>150-800</td>
<td>Scrubber (included)</td>
<td>Y</td>
<td>70-80%</td>
<td>IV</td>
<td>Yes</td>
<td>A1</td>
<td>D1, D2, D3</td>
<td>1 wk</td>
<td>No titanium</td>
</tr>
<tr>
<td>GTI</td>
<td>Specialized cement manufacturing</td>
<td>H</td>
<td>$172 MM (varies)</td>
<td>Not required</td>
<td>Nat. gas, elect.</td>
<td>varies</td>
<td>APC system</td>
<td>Y</td>
<td>90%</td>
<td>IV*</td>
<td>*</td>
<td>A1, A3, A4</td>
<td>D1, D2, D3</td>
<td>1 wk</td>
<td>None listed</td>
</tr>
<tr>
<td>Hydroclave Systems Corp.</td>
<td>Steam-Mixing-Fragmenting/Drying</td>
<td>L</td>
<td>$46,000 to $340,000</td>
<td>Internal grinder</td>
<td>Steam/elect.</td>
<td>Not indicated</td>
<td>Closed system</td>
<td>Y</td>
<td>80%</td>
<td>IV</td>
<td>Yes</td>
<td>A1</td>
<td>D2, D3</td>
<td>4 hr</td>
<td>No cytotoxic, prion</td>
</tr>
<tr>
<td>Mark-Costello Co.</td>
<td>Autoclave or Retort</td>
<td>L</td>
<td>$25,000 to $350,000</td>
<td>Bagged, Optional grinder</td>
<td>Steam/elect.</td>
<td>50-1125 Not req'd</td>
<td>N</td>
<td>30%</td>
<td>IV</td>
<td>No</td>
<td>A3</td>
<td>D3</td>
<td>Supplied</td>
<td>No cytotoxic, prion</td>
<td></td>
</tr>
<tr>
<td>Matrix Technology PTY Ltd.</td>
<td>Chemical</td>
<td>C</td>
<td>Not provided</td>
<td>Not indicated</td>
<td>3 ph Elect.</td>
<td>varies</td>
<td>Closed system</td>
<td>Y</td>
<td>70-80%</td>
<td>III</td>
<td>Yes</td>
<td>A1</td>
<td>D5</td>
<td>1 day</td>
<td>No cytotoxic, prion</td>
</tr>
<tr>
<td>MCM Environmental Technologies</td>
<td>Shredding-Mixing-&quot;Stericid&quot;</td>
<td>C</td>
<td>$70,000 ($14,000 for &quot;junior&quot; version)</td>
<td>Not indicated</td>
<td>Not indicated</td>
<td>Not indicated</td>
<td>Not indicated</td>
<td>Y</td>
<td>Not indicated</td>
<td>IV</td>
<td>No</td>
<td>A1</td>
<td>D5, D6</td>
<td>Not indicated</td>
<td>No cytotoxic, prion, biohazardous</td>
</tr>
<tr>
<td>MedPro, Inc.</td>
<td>Needle destruction</td>
<td>O</td>
<td>$895</td>
<td>Not required</td>
<td>110 V</td>
<td>Filter</td>
<td>Y</td>
<td>50%</td>
<td>III</td>
<td>No</td>
<td>A2</td>
<td>1 hr</td>
<td>Only for needles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MedShred</td>
<td>Sodium Hypochlorite-Shredding (mobile)</td>
<td>C</td>
<td>$450,000</td>
<td>Grinder (included)</td>
<td>440 V</td>
<td>3000</td>
<td>Filters</td>
<td>Y</td>
<td>89%</td>
<td>IV</td>
<td>No</td>
<td>A1, A3</td>
<td>D3, D5</td>
<td>Supplied</td>
<td>Not &gt;2% cytotoxics</td>
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### Table 3 (Continued)
Comparison of Biomedical Waste Treatment Technologies

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Description</th>
<th>Type Key</th>
<th>Capital Cost</th>
<th>Feed Prep.</th>
<th>Energy</th>
<th>Capacity/ Process Flow lb./hr.</th>
<th>Env. Control Measures</th>
<th>Waste Unrecognizable</th>
<th>Waste Vol. Reduct, %</th>
<th>Disinfection Level</th>
<th>Disinfection Level Verification</th>
<th>Advantages (see below)</th>
<th>Disadvantages (see below)</th>
<th>Training</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microtek Medical, Inc. (Iolyser)</td>
<td>Liquids Treatment System</td>
<td>U</td>
<td>Minimal</td>
<td>Canister</td>
<td>N/A</td>
<td>1</td>
<td>Closed system</td>
<td>N</td>
<td>0%</td>
<td>III</td>
<td>No</td>
<td>A1, A2, A3</td>
<td>D5</td>
<td>1 hr</td>
<td>Liquids only; no prions; not 100% blood</td>
</tr>
<tr>
<td>Plasma Pyrolysis Systems</td>
<td>Plasma Pyrolysis</td>
<td>H</td>
<td>$1.3 MM</td>
<td>Boxed</td>
<td>326 kW</td>
<td>360 Boiler</td>
<td>Y</td>
<td>99%</td>
<td>IV*</td>
<td>No</td>
<td>A1</td>
<td>D1, D2, D4</td>
<td>1 wk</td>
<td>No lead; cadmium, mercury</td>
<td></td>
</tr>
<tr>
<td>San-L-Pak</td>
<td>Vacuum-Steam-Compaction</td>
<td>L</td>
<td>$40,000 to $500,000</td>
<td>Not required</td>
<td>25 - 3000</td>
<td>Diffuser/ condenser</td>
<td>Y*</td>
<td>60-80%</td>
<td>IV</td>
<td>Yes</td>
<td>A1, A3</td>
<td>D3</td>
<td>4 hr</td>
<td>No cytotoxic, prion</td>
<td></td>
</tr>
<tr>
<td>Stericycle Inc.</td>
<td>Electro-Thermal Deactivation</td>
<td>L</td>
<td>Not provided</td>
<td>Shredder (included)</td>
<td>Elect.</td>
<td>Not indicated</td>
<td>Not indicated</td>
<td>Y</td>
<td>80%</td>
<td>IV</td>
<td>No</td>
<td>A1, A3</td>
<td>D3</td>
<td>4 hr</td>
<td>No chem, tissue, pathogenic, cytotoxic</td>
</tr>
<tr>
<td>Sterile Technology Industries Inc.</td>
<td>Shredding/ Steam-Mixing/ Drying, Chemical</td>
<td>L</td>
<td>Varies</td>
<td>Shredder (included)</td>
<td>Not indicated</td>
<td>300-5000</td>
<td>HEPA filter</td>
<td>Y</td>
<td>90%</td>
<td>IV</td>
<td>Yes</td>
<td>A1, A3</td>
<td>D3</td>
<td>Not indicated</td>
<td>No cytotoxic, prion</td>
</tr>
<tr>
<td>Thermal Waste Technologies Inc.</td>
<td>Dry Heat Treatment</td>
<td>H</td>
<td>$4,000</td>
<td>Not required</td>
<td>Elect.</td>
<td>3</td>
<td>Filter</td>
<td>N</td>
<td>0%</td>
<td>IV</td>
<td>Yes</td>
<td>A1, A2, A3</td>
<td>D4</td>
<td>1 hr</td>
<td>Small quantities (1 gal) only; no body parts</td>
</tr>
<tr>
<td>Tuttnauer USA Co. Ltd.</td>
<td>Autoclave or Retort</td>
<td>L</td>
<td>$50,000 to $100,000</td>
<td>Not specified</td>
<td>Steam/ elect.</td>
<td>varies</td>
<td>Closed system</td>
<td>N</td>
<td>50%</td>
<td>IV</td>
<td>No</td>
<td>A3</td>
<td>D3</td>
<td>1 day</td>
<td>No cytotoxic, prion</td>
</tr>
<tr>
<td>Vanguard Research Inc.</td>
<td>Plasma Pyrolysis</td>
<td>H</td>
<td>Not provided</td>
<td>Not specified</td>
<td>800-3750 kW</td>
<td>250-4000</td>
<td>Not specified</td>
<td>Y</td>
<td>75%</td>
<td>IV</td>
<td>Yes</td>
<td>A1</td>
<td>D1, D2</td>
<td>1 wk</td>
<td>None listed</td>
</tr>
<tr>
<td>Waste Reduction by Waste Reduction, Inc. (WR)</td>
<td>Alkaline Hydrolysis</td>
<td>C</td>
<td>$132,500 to $1,237,500</td>
<td>Not required</td>
<td>Elect.</td>
<td>1-3000</td>
<td>Not req'd</td>
<td>Y</td>
<td>97%</td>
<td>IV</td>
<td>No</td>
<td>A1, A3</td>
<td>D3, D5</td>
<td>2 days</td>
<td>No aluminum</td>
</tr>
</tbody>
</table>
authority indicating that the system will "totally destroy all pathogens which have any potential to be harmful to health and the environment," or a sterilization assay report showing laboratory test results for destruction of B. stearothermophilus, are examples of such verification. This column indicates "Yes" if such verification was provided, and "No" if not.

3. All listed systems shall not be used to treat radiological (nuclear) waste. Consult manufacturer for more specific information regarding limitations.

4. Treated waste is unrecognizable if optional shredder is used.

5. 0% waste volume reduction generally is associated with technologies that use a small amount of mass (i.e., a solidifying disinfectant) and volume to the waste.

**Advantages**

A1 Treated waste is suitable for landfill disposal
A2 Relatively low capital cost
A3 Utilizes well-proven technology

A4 Treated waste is completely useable as cement product

**Disadvantages**

D1 Relatively high capital cost
D2 Maintenance requirements may be extensive
D3 Possible odors or other emissions unless Air Pollution Control system is well maintained
D4 Single use containers required (adding to operating costs)
D5 Chemical and waste chemical management and disposal required
D6 Proprietary disinfectant required (adding to operating costs)


Philippines Republic Act No. 8749, otherwise known as the "Philippine Clean Air Act of 1999."

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Gas-phase Ozone: Assessment of Biocidal Properties for the Indoor Environment—A Critical Review

Eugene C. Cole
Brigham Young University, Provo, Utah

Abstract

This report provides a detailed review of the scientific literature regarding the biocidal activity of gas-phase ozone. Many claims about its efficacy in reducing microbial contamination have been made by the manufacturers of ozone generators, which have unfortunately found their way into the popular press. However, this review of the peer-reviewed, published, scientific literature has found no appreciable antimicrobial effect of gas-phase ozone on either airborne or surface microorganisms. Its potential role in the control of biological pollution in the indoor environment is not substantiated by scientific investigations.

Introduction

This report addresses the biocidal activity of gas-phase ozone (O₃) in the indoor environment. While long used and recognized effective for the deodorization of smoke-damaged furnishings, recent commercial promotion of gas-phase ozone has purported, through aggressive marketing to consumers, to be effective at inactivating microorganisms, especially molds, in the air and on a variety of surfaces and materials in indoor environments at low concentrations (e.g., 0.04 ppm). A careful review of the published literature, both historically and more recently, however, provide substantial data to the contrary.

Manufacturers of gas-phase ozone generators, particularly those packaged as air cleaning devices, lack the competent and reliable scientific evidence necessary to support far-reaching claims of killing airborne or surface molds with continuously generated low concentration ozone. Similarly, the use of high concentration ozone (>0.08 ppm) to effectively remediate (kill/inactivate) mold contamination on surfaces, such as within wall cavities, ceiling spaces, and HVAC ducts, remains unsupported by scientific evidence. Typically, such devices have never undergone valid, independent, and controlled laboratory efficacy testing, nor applied effectiveness testing in actual indoor environments, wherein the data generated were based on technically standardized, reproducible, and quality-controlled protocols deemed acceptable to the scientific community.

While high concentration (0.5-9.9 ppm) gas-phase ozone has been shown to inactivate some spore-forming and otherwise resistant microorganisms to some degree at high relative humidity (RH) on inert surfaces in the laboratory, as discussed in this review, there is no evidence of any degree of effectiveness on a variety of building materials in actual indoor environments. The recommended remediation of microbial contamination in indoor environments involves the physical removal of contaminated materials followed by thorough cleaning of the surrounding environment (Macher, 1999; USEPA, 2000). In particular, no studies confirm the antimicrobial efficacy of low- or high-concentration gas-phase ozone against microbial contamination on building, finishing, or furnishing materials in the indoor environment.
Scientific Background

Evaluation of Biocide Efficacy

A biocide may be defined as a chemical agent that inactivates (i.e., kills or prevents reproduction) of one or more groups of microorganisms, which includes bacteria, fungi, viruses, mycobacteria, and parasites. Efficacy may be defined as the demonstrated capability of an entity to produce a desired effect. Biocide efficacy is the capability of a liquid or gas-phase chemical to inactivate specific challenges of microorganisms under defined conditions. Efficacy is normally assessed in a controlled laboratory environment.

A variety of chemical, biological, and environmental factors, in combination, determine the efficacy of a particular biocide. These include, among others, chemical concentration, pH, temperature, relative humidity (RH), contact time, presence or absence of organic matter, surface or substrate composition, and microorganism type, quantitative challenge, and tendency toward monodispersion (singly separated cells, spores, viruses, or other units) or aggregation (clumping). Thus, efficacy of a biocide can only be defined under the specific set of circumstances under which it was tested. Efficacy may or may not relate to how the product actually performs as used in the real-world environment.

Efficacy of Gas-phase Ozone

The scientific literature addresses both aqueous ozone and gas-phase ozone. Both can be markedly different in terms of antimicrobial efficacy and potential application.

Aqueous ozone. Ozone dissolved in water is recognized as an effective biocide in low concentration against vegetative microorganisms such as bacteria, fungi, viruses, and parasites under ideal laboratory conditions (Hall and Sobsey, 1993; Wickramanayake, 1991). However, inactivation of these organisms in wastewaters where microbial concentrations are very high and there is considerable organic matter challenge requires larger doses of ozone and longer contact times.

Gas-phase ozone. Gas-phase ozone has been evaluated for its capability to inactivate microorganisms in the air and on surfaces. The survival or inactivation of microbial aerosols is dependent upon a number of varied intrinsic and interrelated environmental factors (Cole & Cook, 1998).

Of great importance in this regard is the fact that airborne microorganisms or those on surfaces, whether bacterial cells, fungal spores, or virus particles, tend to occur most often in aggregates and typically in association with organic dust particles. These conditions provide a measure of protection from biocidal activity. Microbial clumping may preclude some cells or spores from having physical contact with the biocide. Likewise, organic matter may physically preclude biocide exposure and/or exert a neutralizing effect, depending upon its nature. This was dramatically demonstrated in a study where gas-phase ozone was introduced into flasks of actively growing *Achromobacter* bacteria (Ingram & Haines, 1949). Results showed that 1,000-2,000 ppm ozone had no effect on growth rate, 2,450 ppm began to affect the growth cycle, and 3,890 ppm was required to arrest all growth, with complete kill only after 30 hours exposure. Also exemplifying this concept, Elford and van Den Ende (1942) found that airborne bacteria are covered with a protective coating of organic matter, as in aerosols naturally emitted during a sneeze or cough, gas-phase ozone at low concentration (0.2-0.3 ppm) had little effect. They also found that bacteria that settled onto surfaces are generally more resistant to ozone than when initially expelled from the respiratory tract.

The fact that microorganisms dried on a surface are intrinsically more resistant to germicidal inactivation forms the basis for microbial challenges dried onto steel or porcelain, as used in the standard Association of Official Analytical Chemists (AOAC) test methods required by the USEPA to generate efficacy data for the registration of chemical germicides. Also, it is well recognized that different types of microorganisms constitute a scale of innate resistance to inactivation, based upon their structural physiology and other unknown factors (Cole & Robison, 1996).

Biocidal Activity of Gas-phase Ozone

Well-controlled laboratory chamber studies sponsored by the USEPA have confirmed the lim-
imated efficacy of gas-phase ozone at high concentration and prolonged contact time against a variety of fungal and bacterial pollutants dried on surfaces (Foarde et al., 1997). Researchers first tested high concentrations (10^5-10^6) of mold spores, bacterial spores, and yeast cells, dried on glass surfaces. Samples were exposed continuously for 23 hours to ozone concentrations ranging from 0.5-9.9 ppm at 90% relative humidity (RH), and to 2.5-9.9 ppm at 30% RH. Yeast cell inactivation at 90% RH reached a 3 log (10-fold) reduction at 5.5 ppm, but inactivation was minimal at 30% RH. *Penicillium chrysogenum* and *P. glabrum* mold spores showed gradual inactivation dependent upon ozone concentration. At 90% RH a 3-log reduction was detectable at 6.2 ppm, while 30% RH required 9.8 ppm. The greatest challenge was shown to be the highly resistant spores of the *Streptomyces* bacterium, where negligible inactivation was observed at both high and low level RH, even at high concentration gas-phase ozone (7.3-9.9 ppm). Such results were similar to a previous study that investigated the inactivation of *Bacillus* spores on filter paper and glass fiber filters, and found that results of inactivation with 0.5-3.0 ppm ozone varied according to RH, with little inactivation occurring at RH of 50% or below (Ishizaki et al., 1986). Similarly, evaluation of inactivation of vegetative bacteria and yeast cells on stainless steel exposed to 2 ppm ozone for 4 hours showed varied kill, as well as diminished effectiveness in the presence of organic matter (Moore et al., 2000).

Of greatest significance is the second phase of the USEPA study, where researchers repeated the testing using mold spores of the two *Penicillium* species, RH of 90%, and the concentration of gas-phase ozone set to a level of 9 ppm. This time, however, the 10^5-10^6 concentrations of spores were not inoculated onto glass, but onto actual building materials to include two types of fiberglass ductliner, fiberboard duct, two types of ceiling tile, and galvanized steel. Even though exposure time remained at 23 hours, no appreciable inactivation of the spores on any of the materials was detectable compared to initial test concentrations. In fact, testing with the ceiling tiles would not permit gas-phase ozone concentrations in the chamber to rise above 5 ppm, demonstrating the neutralizing effect that materials can have on gas-phase ozone at the microorganism/material interface.

**Multiple Factors Limit Effectiveness**

Effectiveness of a biocide is the measure of its efficacy in the real-world environment. Since gas-phase ozone has been shown to be ineffective in the laboratory under controlled conditions against a variety of microorganisms on actual building materials, effectiveness in an actual indoor environment under uncontrolled conditions would not be expected. Other factors against ozone’s effectiveness include the inability of the gas to be delivered to all building spaces, difficulty in maintaining concentration and relative humidity over time, airflow and internal building pressures, and its reactivity with certain materials (such as rubber and electrical wire insulation with unsaturated carbon-carbon bonds).

**A Critical Review of Often-cited Literature**

Ozone-generating device manufacturers, while typically lacking effectiveness data for their units over and above natural microorganism death rates due to desiccation, lack of essential nutrients, or ultraviolet exposures, often cite various scientific published papers as evidence of the efficacy and/or effectiveness of gas-phase ozone. A closer look at such references, however, results in significantly different conclusions. For example, the papers “Ozone Inactivation of Cell-Associated Viruses” (Emerson et al., 1982), and “The Biological Effects of Ozone on Representative Members of Five Groups of Animal Viruses” (Bolton et al., 1982) have been pointed to for efficacy data for gas-phase ozone. The Emerson paper reports studies relevant to water and wastewater disinfection, as suspensions of cell-associated or unassociated viruses were ozonated at varying times and conditions. In fact, study data show a lack of ozone efficacy, as it is stated in the report that “in conclusion, cell-associated enteric viruses were protected from inactivation by exposure to ozone.” A major issue is that the study was not an applied field evaluation of gas-phase ozone against naturally resistant or dried organisms in the indoor environment, but a laboratory evaluation of aqueous ozone efficacy. Similarly, the Bolton paper presents data relevant to the inactivation of virus suspensions using gas-phase ozone, re-
sulting again in an aqueous ozone situation not relevant to addressing active microbial growth or its dried residuals in the indoor environment.

Other cited papers present similar interpretation problems, such as "Ozone Decontamination of Bioclean Rooms" (Masaoka et al., 1982). Here again, the challenges were wet organism suspensions on filter paper, in water, or soaked in a sponge, that actually represent aqueous ozone conditions rather than dried or actively growing microorganisms. In a survey paper, "Application of Ozone in Control of Mold, Bacteria, and Odors" (Nagy, 1957), ozone generated by an ultraviolet lamp for odor control is reviewed, and a determination made that heavy growths of mold and bacteria are not destroyed on surfaces. Also, studies in which a UV lamp is used to generate ozone make it difficult to distinguish germicidal effects from the ozone versus the UV itself, which is known to have antimicrobial properties.

Required Approach to Evaluation of Effectiveness

It must be remembered that while many studies in the scientific literature address the efficacy or effectiveness of ozone, the data generated in each represent the many, varied, and specific conditions under which the testing was done at that time. While such data are useful for general knowledge of, and in some cases specific applications for, ozone, one must be very cautious about taking selected data and extrapolating the results to any device that generates ozone. The only sure way to demonstrate that an ozone-generating device is effective as claimed is for test it independently, first for efficacy under controlled laboratory conditions and second for effectiveness under actual in-use or field conditions in the indoor environment, controlling all variables except those that are being investigated. Both laboratory and field studies must be designed and carried out according to concepts acceptable to the scientific community. This includes designing the protocols and conducting the work in such a fashion that the study can easily be reproduced by other investigators.

Microbial Residuals

Of great concern with the use of any biocide is the residual that remains if microorganisms are killed or otherwise inactivated. Residuals of killed bacteria and fungi are still regarded as potential indoor pollutants. When gram-negative bacteria are killed and their cell walls are disrupted, those fragments are known as endotoxin—highly reactive molecules which may become airborne and be inhaled. Endotoxins are very stable and can be reliably destroyed only by extreme heat. They are recognized as causing pulmonary inflammation and irritation, and potentiating the allergic response (Rylander & Jacobs, 1994). Endotoxin exposures have been implicated in diseases such as byssinosis and humidifier fever. Likewise, mold spores that have been killed can still retain intact antigens capable of inciting an allergic response in a sensitized individual. Gas-phase ozone has never been demonstrated to destroy or otherwise neutralize such mold antigens.

In addition to molds, some air-cleaning device manufacturers may tout the efficacy of gas-phase ozone to destroy, neutralize, or inactivate a variety of other allergens, such as those from dust mites or cats, although no published study data have been identified. At the present time, the most rational approach indicates that periodic cleaning (extraction) and routine maintenance (high-efficiency vacuuming) of carpet and upholstery, as well as similar attention to mattresses, along with indoor moisture control, will reduce dusts generated from those sources and consequently the allergens associated with them (Cole et al., 2000; Franke et al., 1997).

Health Effects Claims

No positive health effects resulting from the application of gas-phase ozone to an indoor environment have ever been reported. On the contrary, ozone is a major respiratory irritant, wherein as little as 0.08 ppm exposure can result in cough, chest discomfort, lung inflammation, and increased airway reactivity (Cotran et al., 1999). Current national health standards for ozone exposure include the EPA’s National Ambient Air Quality Standard of a maximum 8-hour average concentration of 0.08 ppm, while the National Institute for Occupational Safety and Health (NIOSH) recommends that an upper limit of 0.10 ppm not be exceeded at any time, with a threshold of 5.0 ppm considered imme-
diately dangerous to life or health (NIOSH, 2003). In this regard, there are no recommendations for specific respirator cartridges deemed adequate to protect workers from exposure and potential health effects from high concentration gas-phase ozone.

Manufacturers utilizing product marketing claims that state or imply a positive human health effect resulting from its use, such as “allows occupants to breathe easier,” “reduces numbers and severity of respiratory infections,” or similar claims, should be required to prove such claims through a randomized, controlled, clinical trial in which biological and other markers of health are monitored for a lengthy period in both intervention and control groups. Such studies minimally require 18-24 months or more to complete, are overseen by physicians, and require a detailed study design approved by an Institutional Review Board for the protection of human subjects. Biological and health markers typically include daily peak flow measurements, number of asthmatic attacks, number of physician and hospital visits, use of prescription medications, etc. While typically costing in excess of $1 million, such studies are the only way to provide meaningful evidence or not of whether regular and long-term use of the ozone-generating product or device results in positive health effects.

**Conclusion**

In summary, a review of the peer-reviewed, published, scientific literature has shown no appreciable antimicrobial effect of gas-phase ozone on either airborne or surface microorganisms, relative to significant control of biological pollution in the indoor environment. In general, considering the extent of variability of types and concentrations of biological pollutants, their spectrum of intrinsic inactivation resistances, their range of recognized reservoirs, and the extreme variability in environmental conditions relative to temperature, RH, air flow, and organic matter interference among others, there remains no recognized antimicrobial effectiveness nor recommended protocol for the use of gas-phase ozone for the indoor environment.

**References**


Comparative Analysis of Biosafety Guidelines of the USA, WHO, and Russia (Organizational and Controlling, Medical and Sanitary—Antiepidemiological Aspects)

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State Research Center of Virology and Biotechnology "Vector" (SRC VB "Vector"), Koltsovo, Novosibirsk Region, Russia

Abstract

Carrying out research for the purpose of prophylactic medicine with dangerous, highly infectious causative agents of disease requires appropriate safety conditions. In addition, the need for appropriate biological safety and security considerations is acquiring an ever-growing national and international importance given the existing threat of the use of these agents by terrorists. Because of these facts, the harmonization of national safety guidelines regulating the organization and work with Hazard Group I-IV pathogens in different countries is gaining more importance and relevance. This paper presents a comparative analysis of safety guidelines and regulations from the United States contained in the Centers for Disease Control and Prevention—National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories (BMBL), the World Health Organization Laboratory Biosafety Manual (WHO LBM) and Russia’s Sanitary Rules (SRs).

Introduction

Carrying out research for the purpose of prophylactic medicine with dangerous, highly infectious causative agents of disease requires appropriate safety conditions. Given the growing scope of international cooperation in this field and the exchange of work between scientists, there is an ever-growing national and international importance. These facts, along with the reality of existing threats from the use of highly dangerous pathogens by terrorists and the need for appropriate biological safety conditions for work, and storage and transportation of these agents, have drawn attention to the increased global importance of, and relevance to, the concept of harmonization of national biological safety guidelines that regulate work with Hazard Group I-IV pathogens in different countries. The need to develop national and joint international contingency programs for possible bioterrorist attacks also makes harmonization necessary. The comparative analysis of biosafety guidance of the USA, the WHO, and Russia carried out at SRC VB “Vector,” and the development of recommendations and proposals based on these analyses to be included in the new edition of the Russian Sanitary Rules, could be regarded as the first step in this direction. The urgency and practical value of this work for SRC VB “Vector” are explained by the fact that the Center is one of 17 Russian official institutions possessing specialized collections of Hazard Groups I-IV microorganisms. In particular, the Center possesses a collection of Hazard Groups I-IV viruses and is a WHO Collaborating Center for diagnosing orthopoxviral infections. In addition, a repository of smallpox virus strains and
DNA was founded and is functioning. A large number of cooperative research projects and programs such as the Russian-American smallpox program are being carried out within the scope of international cooperation.

Comparative Analysis

A comparative analysis of the Russian SRs (SRs 1993, 1994, 1999, 1996), the U.S. BMBL (CDC-NIH, 1999), and the WHO LBM (WHO, 1993) has been conducted. The comparative analysis found differences among these documents including organizational, regulatory medical, and antiepidemical aspects, which have been identified and are listed below:

- Technical execution of the documents
- The status of the documents
- The content and volume of the documents
- The system of obtaining permission to work
- The classification of pathogenic microorganisms
- Biosafety levels for working with laboratory animals
- The requirements and control of admission of personnel to work with biological material
- Personal responsibility for working with biological materials
- Shipment and transfer of biological agents
- Contingency plans and emergency procedures
- Risk assessment
- Primary and secondary containment barriers
- Organization of training

Technical Execution and Arrangement

Analysis of these documents revealed differences concerning their technical execution and arrangement. Biosafety issues, recommendations, and solutions are considered in four separate Russian SRs regulating various biosafety aspects, while in the BMBL and the WHO LBM guidelines, they are presented as integral documents (SRs 1993, 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993).

The Status of the Documents

The SRs, BMBL, and LBM have differences in their regulatory status and emphasis. The SRs are regulations (sanitary norms) that are considered mandatory by any institution regardless of the department it refers to or the form of the property. Disciplinary, administrative, and criminal proceedings can be instituted against organizations violating these SRs. The BMBL, however, is a guideline that provides the best recommendations for application of safety practices and risk assessment and is of particular importance in providing guidance in the building of new laboratories or remodeling existing ones. In the United States, the BMBL is utilized for regulatory purposes to evaluate a facility’s suitability for working with “Select Agents,” which are pathogenic agents that have been placed on a restricted transfer and possession list in the United States because of their potential use as a biological weapon for terrorists. Besides those for “Select Agents,” these recommendations also play an advisory role rather than being a regulatory obligation. The BMBL was developed as an advisory guideline and, in the opinion of the authors, should be updated to provide clear regulatory guidance. The WHO LBM has a more practical role, contains reliable information, and is a compact and convenient directory for practical use.

The Content and Volume of the Documents

The next group of differences concerns the content of the documents. The BMBL contains individual sections on risk assessment, a brief description of the characteristics of the infectious agents, and appendices that describe the biosafety cabinets which the SRs lack. The risk assessment allows for the development of different facilities and establishes various procedures for different levels of risk when working with the same agent based on the procedures used. For example, there is generally a lower risk working with a diagnostic specimen of a pathogenic agent than working with the same agent in aerosol format.

The BMBL also contains the following sections which are not present in the SRs or the WHO LBM:
- A separate list of highly dangerous animal pathogens
- Reference material, including addresses for obtaining additional information;
- Materials on immunoprophylaxis
- Physical safety in microbiology and biomedical laboratories
• An integrated pest management (IPM) program for pest management (e.g., flies and cockroaches)
• Principles of work with toxins of biological origin
• A description of work with human and non-human primate cells and tissues

The WHO LBM (WHO, 1993) contains the following sections (or appendices) which are not included in the SRs (SRs, 1994, 1999, 1996) or the BMBL (CDC-NIH, 1993):
• A description of laboratory equipment
• Chemical, fire, and electrical safety, as well as requirements for the training of personnel and a training program
• A safety checklist
• Separate material on personnel immunization and educational information on microbiological safety

The SRs (1994, 1999, 1996) contain individual sections (or appendices) which are not contained in the BMBL (WHO, 1993) or the WHO LBM (WHO, 1993) on:
• Procedures for catching, transporting and maintaining wild vertebrates for carrying out experiments
• Work in hospitals, isolation wards, and observation rooms
• Medical surveillance of the population
• Disinfection and patholoanatomical work in the foci of highly dangerous infectious agents
• A procedure for employees leaving institutions working with biological materials
• Disinfection devices and methods used in the work with pathogenic microorganisms
• Decontamination procedures for different objects contaminated with pathogenic microorganisms
• Chemical tests for controlling temperature parameters of the function of steam sterilizers
• A bacteriological method for controlling steam sterilizer efficiency
• A procedure for the replacement of HEPA filters in an exhaust ventilation system and determination of their efficiency
• Requirements for testing contaminated media in mobile disinfection chambers
• Requirements for testing sewage water for pathogenic microflora

However, in contrast to the WHO LBM, the SRs do not have separate sections (appendices) on chemical, fire, and electrical safety; training of personnel and a training program; safety checklist; or educational information on microbiological safety (SRs 1994, 1999, 1996; WHO, 1993).

The SRs also have separate annexes that describe the functions and scope of activities of the commissions that regulate the observance of biological safety requirements at the institution (enterprise). In contrast to both the BMBL and the WHO LBM, the SRs describe in detail the procedure for interested institutions to obtain permission to work with Hazard Groups I-IV microorganisms and recombinant DNA molecules from the bodies of the State Sanitary-Epidemiological Inspection Committee of the Russian Federation, as well as the necessary requirements and documents to obtain this permission. Standard permissions to work with Hazard Groups I-IV microorganisms and recombinant DNA are given for a period of 5 years, while work with aerosols is given for a period of 2 years (SRs 1993, 1994, 1999, 1996).

In contrast to the SRs, the WHO LBM lacks individual sections (or appendices) on procedures of catching, transporting, and keeping wild vertebrates for use in experiments; work in hospitals, isolation wards, and observation rooms; medical surveillance of the population; and disinfection and patholoanatomical work in the foci of highly dangerous infections. In contrast to the U.S. BMBL, there are no sections (appendices) on risk assessment, the brief characteristics of infectious agents, a listing of highly dangerous animal pathogens, complex programs for pest management, descriptions of work with human and primate cells and tissues, and principles of work with toxins of biological origin (SR 1993; SR 1994; SR 1999, CDC-NIH, 1999; WHO, 1993).

Based on the above information, it is evident that there are significant differences in the content of the three documents reviewed. The analysis shows that there are far fewer differences between the BMBL and the WHO LBM than there are between the SRs and the BMBL and WHO LBM. However, on the whole, these differences neither hinder the understanding of these documents nor lower their practical value. Nevertheless, we consider it expedient to supplement the SRs with the missing sections and materials.
The System of Obtaining Permission to Work

In contrast to the U.S. BMBL and the WHO LBM, the SRs describe in detail the procedure for interested institutions to obtain permission to work with Hazard Groups IV microorganisms and recombinant DNA molecules from the organs of the State Sanitary-Epidemiological Inspection Committee of RF, as well as the requirements and documents necessary for obtaining this permission. Standard permissions to work with Hazard Groups IV microorganisms and recombinant DNA molecules are given for a period of 5 years, while work with aerosols Hazard Groups IV microorganisms is given for a period of 2 years (SRs 1993, 1994, 1999, 1996).

The Classification of Pathogenic Microorganisms

Figure 1 shows the differences among the Russian, WHO, and U.S. classifications of pathogens, which shows that the risk groups are reversed. In the Russian system of classification, Group IV is the least hazardous group while in the United States, Biosafety Level 1 (BSL-1) is the lowest risk group and in the WHO classification system, it is Risk Group I. Group I in the Russian system contains the most dangerous and exotic organisms while the U.S. system lists these agents as BSL-4 and the WHO as Risk Group IV. There are also differences between the Russian and U.S. systems in the individual classification of microorganisms within the hazard groups.

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**Figure 1**
Risk Group Comparisons

<table>
<thead>
<tr>
<th>US BMBL</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>BSL 1 (ABSL 1)</em></td>
<td>LBM</td>
</tr>
<tr>
<td>Defined organisms</td>
<td>RISK</td>
</tr>
<tr>
<td>Not known to cause disease in healthy adults</td>
<td>GROUP I</td>
</tr>
<tr>
<td>Examples: Lactobacillus, Baclovirus</td>
<td>Basic Labs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>US BMBL</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>BSL 2 (ABSL 2)</em></td>
<td>LBM</td>
</tr>
<tr>
<td>Moderate-risk agents present in the community disease of varying severity</td>
<td>RISK</td>
</tr>
<tr>
<td>Examples: Salmonella, Hepatitis, Herpes simplex</td>
<td>GROUP II</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>US BMBL</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>BSL 3 (ABSL 3)</em></td>
<td>LBM</td>
</tr>
<tr>
<td>Indigenous or exotic agents, aerosol transmission serious and potentially lethal infection</td>
<td>RISK</td>
</tr>
<tr>
<td>Examples: Brucella, Rift Valley Fever, VEE</td>
<td>GROUP III</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>US BMBL</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>BSL 4 (ABSL 4)</em></td>
<td>LBM</td>
</tr>
<tr>
<td>Dangerous or exotic, high-risk agents life threatening disease</td>
<td>RISK</td>
</tr>
<tr>
<td>Examples: Ebola, Marburg, Lassa, Machupo</td>
<td>GROUP IV</td>
</tr>
</tbody>
</table>

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**RUSSIAN SR**

<table>
<thead>
<tr>
<th>Classification of microorganisms</th>
<th>Classification of Containment Labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group IV</td>
<td>ZONE III</td>
</tr>
<tr>
<td>Group III</td>
<td>ZONE II</td>
</tr>
<tr>
<td>Group II</td>
<td>Containment Labs</td>
</tr>
<tr>
<td>Group I</td>
<td>ZONE I</td>
</tr>
</tbody>
</table>
The same microorganism may be classified under different groups (Figure 2). For example, the causative agent of tuberculosis is listed as a BSL-2 pathogen in the U.S. BMBL while the SRs list it as a Group III hazard. Similarly, the agents of Congo-Crimean hemorrhagic fever, Omsk hemorrhagic fever, and Central European tick-borne spring/summer encephalitis are all listed as BSL-4 pathogens in the U.S. BMBL, while the Russian CRs lists them as Group II pathogens. It should also be noted that in the U.S. BMBL Yersinia pestis can be classified either under BSL-2 or BSL-3, depending on the risk level (e.g., the potential for droplet or aerosol production, work with antibiotic-resistant strains, or the use of large quantities or high concentrations of infectious materials). This situation considerably hinders any mutual understandings when international research groups carry out collaborative projects. In view of this, we prepared recommendations for a new edition of the SRs for the State Sanitary-Epidemiological Control of the Russian Federation, to include matching the numeration of pathogens in the Russian classification with those in the international classifications. Furthermore, it was also recommended that tuberculosis pathogens (with multidrug resistance) be classified into Hazard Group II which includes more dangerous pathogens, instead of Hazard Group III where it is now located. Additionally, monkeypox virus, which is listed as a BSL-2 pathogen in the BMBL, is not even listed as pathogen in the SRs (SRs 1994, 1999, 1996).

**Figure 2**

Agent Classification Comparison

<table>
<thead>
<tr>
<th>US BMBL</th>
<th>RUSSIAN SR</th>
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<tbody>
<tr>
<td>BSL 4</td>
<td>GROUP I</td>
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<tr>
<td>Varsiola virus</td>
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<tr>
<td>Ebola virus</td>
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<td>Hepatitis simiae</td>
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<td>Machupo virus</td>
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<td>Marburg virus</td>
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<td>Junin virus</td>
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<td>Lassa fever virus</td>
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<td>Congo Crimean hemorrhagic fever</td>
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<td>Kyasanur Forest virus</td>
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<td>Guanarito virus</td>
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<td>Central European tick-borne encephalitis virus</td>
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<td>Saba amnaviiruses</td>
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<td>Omsk hemorrhagic fever</td>
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<tr>
<td>BSL 3</td>
<td>GROUP II</td>
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<tr>
<td>Bacillus anthracis</td>
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<tr>
<td>Brucella melitensis</td>
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<tr>
<td>Burkholderia mallei and pseudomallei</td>
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<tr>
<td>Chlamydia pneumonia avian strains</td>
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<tr>
<td>Coxiella burnetii</td>
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<td>Francisella tularensis</td>
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<tr>
<td>Hantaviruses</td>
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<tr>
<td>Japanese B encephalitis</td>
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<tr>
<td>Lympioctylic choriomeningitis</td>
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<tr>
<td>Nairobi Sheep</td>
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<td>Rabies virus</td>
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<td>Rockettia ricketsii</td>
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<tr>
<td>St. Louis encephalitis</td>
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<td>Venezuelan equine encephalomyelitis</td>
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<td>West Nile fever virus</td>
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<td>Yellow fever virus</td>
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<tr>
<td>BSL 2</td>
<td>GROUP III</td>
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<tr>
<td>Yersinia pestis</td>
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<tr>
<td>Mycobacterium tuberculosis</td>
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The SRs (Figure 1) contain three biosafety levels (zones) instead of four. The numeration and distribution by risk level are reverse to those in the American and international classifications. We prepared recommendations concerning the change of numeration of biosafety levels in the Russian classification by the degree of danger—from the 1 to 3 (from the absence of hazard to high danger). These recommendations were submitted to the State Sanitary-Epidemiological Control of the Russian Federation. The introduction of biosafety level 1 in the U.S. BMBL and Risk Group I in the WHO, which are used for work involving well-characterized agents not known to cause disease in healthy adult humans, is practically analogous to biosafety level 2 and Risk Group 2 and, in our opinion, is somewhat artificial. The presence of this level not only erodes the borderline between these two levels, but also hinders the process of forming a clear line of qualitative transition from low biosafety levels to higher ones. Students and laboratory workers should feel a multiple increase of danger (risk) and responsibility for themselves and the surrounding community when working with pathogens at higher risk levels. The level of the “clean” zone (the 1st zone in the new SRs, which would be equivalent to the current BSL-1 or RG-I) would be a solution for the problems mentioned above (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993; Stavskiy, Hawley & Crane, 2002).

**Biosafety Levels for Working with Laboratory Animals**

In the SRs, animal studies are not classified separately as they are in the U.S. BMBL, which classifies animal studies into Animal Biosafety Levels (ABSL-1, ABSL-2, ABSL-3, and ABSL-4) based on the degree of hazard. According to the SRs, the primary and determining factors for work with animals is the degree of hazard posed by the microorganism being studied (SRs 1994, 1999) and the work with animals infected with Hazard Groups I-IV (SRs) is performed only under conditions of the “dirty” zone (1st zone). Safety requirements and recommendations for organizing animal studies under conditions of the 1st zone are analogous to those of the U.S. ABSL-1 though ABSL-4. Unlike the U.S. BMBL and the WHO LBM, the SRs also consider requirements for organizing and carrying out work with animals and ectoparasites under field conditions (procedure for catching, transportation and analysis) (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993; Stavskiy, Hawley & Crane, 2002).

**The Requirements and Controls for Admission of Personnel to Work with Biological Material**

The requirements and controls for admission of personnel to work with biological material are described in more detail in the SRs than the U.S. BMBL or the WHO LBM. The work with Hazard Groups I-IV pathogens requires:

- Higher or secondary medical, biological, or veterinary education and special training
- The permission of the director of the institute to take the job
- The absence of contraindications against vaccine prophylaxis and treatment with specific preparations
- A medical examination before taking the job
- An annual medical examination during employment

Permission to work with experimental material is given by the order of the director of the institute every 2 years after checking the individual’s knowledge of safety. Engineering and maintenance staff, as well as disinfecting and cleaning personnel, are trained within the department and permitted to work in accordance with the official duties and institutional order. The director of the institute gives temporary engineering and technical personnel permission to enter the laboratory. These personnel can visit the laboratory only after cessation of work and disinfection of the laboratory and only if accompanied by a department employee. The visit is then recorded in a registry. Temporary specialists (medical and veterinary doctors, biologists, etc.) are admitted to the rooms where biological material is handled only after receiving written permission from the director of the institute. The purpose of the visit is also recorded in the registry. Employees who come in contact with biological material of Hazard Groups I-IV pathogens need to be vaccinated prior to working with these pathogens (with the exception of *Vibrio cholerae*). Those individuals having contraindications for vaccination are permitted to work only with a
special institutional order. Additionally, individuals having contraindications against vaccination are not permitted to work in aerosol laboratories or with material infected or suspected of being infected with the causative agent of Q (Coxiella burnetii) (SR 1994). Only specialists who hold higher and secondary education experience and who have appropriate training are permitted to work with Hazard Groups I-II pathogens (SR 1999). All employees working with Hazard Groups I-IV pathogens must undergo daily medical surveillance with thermometry (temperature check for fever), except those working with Vibrio cholerae and toxins of biological origin. The medical surveillance results are then recorded in a special registry and signed by a responsible doctor (or scientific worker). For individuals working with the Vibrio cholerae pathogen, obligatory tests for vibrio-carriage are required if the individual exhibits gastrointestinal malfunctions. All employees working with Hazard Groups I-II pathogens are set up to receive a regular medical evaluation. Each employee must inform the director of the institute or an official on duty about any illness or adverse medical symptoms before continuing to work. The institution’s doctor would be sent to the home of the ill employee for an epidemiological investigation and to determine the need for isolation. The result of the visit is recorded in a registry and reported to the director of the institute. The visit of a private doctor of the general medical system is allowed only after that of the institution’s doctor; critical care indications are an exception and doctor care is allowed under these circumstances. The patient and his or her relatives would be required to inform the doctor from the general medical system about the nature of the patient’s work and also to inform the head of the department where he or she works about the incident. Employees who cannot come to work for some reason are required to inform the head of the department within 2 hours of when they are expected to report to work. If an employee does not come to the institution 2 hours after his or her normal start time and nobody knows where he or she is, the head of the department must take the necessary measures to learn where the employee is and why he or she is absent from the workplace (SRs 1994, 1999).

The U.S. BMBL and WHO LBM requirements for permission for the scientific, engineering, and maintenance and support staff to work with biological materials are as follows:

- Special training in the recognition of disease and handling of pathogens
- A medical examination before taking or changing a job
- Medical surveillance during employment controlled by the head of the laboratory

In addition, a risk assessment should be conducted to determine when vaccination is obligatory (mandatory) or recommended, what samples should be taken for analysis, and the type of medical examination of personnel to be performed.

The head of the laboratory is responsible for:

- Controlling access to the laboratory and restricting access to designated personnel
- Organizing and carrying out laboratory activities
- Instructing all laboratory and support staff concerning any potential risk factors relating to the work being conducted
- Informing laboratory staff about appropriate biosafety precautions
- Ensuring that procedures are in place to check for contamination
- Revising the instructions for work with biohazardous agents annually
- Organizing additional instructions and training of personnel

According to the WHO LBM, personnel working with pathogens of Risk Groups III-IV (international rating system) should have a special card certifying that they are working with these agents. The card should indicate the names of the head of the laboratory and the consulting doctor or safety officer (Stavskiy, Hawley & Crane, 2002).

The SRs describe a clearer and more rigid system of requirements and controls to admit personnel to work with biological material and request medical aid than either the U.S. BMBL or the WHO LBM. This allows for taking timely emergency therapeutic and antiepidemological measures (within several hours). All the personnel performing a cycle of work with Hazard I-II pathogens (Russian classification) are surveyed by the Biosafety Service every 24 hours, both during the working hours and after work (a more rigid system of requesting medical aid, prompt...
measures taken if an employee does not come to work, etc.). The U.S. BMBL and the WHO LBM do not contain rigid requirements about medical control after the working day.

**Personal Responsibility for Working with Biological Materials**

As the analysis has shown, the SRs contain a rather complete description of a structure for distributing responsibility among all personnel participating in organizing and carrying out work with infectious materials. However, in contrast to the U.S. BMBL and the WHO LBM, nothing is said about the responsibility of personnel subordinate to the head of laboratory. This is a serious flaw, especially in organizing and carrying out work with highly dangerous pathogens. According to the SRs and in contrast to the U.S. BMBL and the WHO LBM, the Commission controlling biological safety requirements is an executive and consultative entity that has a wider range of responsibilities compared to analogous structures described in the U.S. BMBL and the WHO LBM (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993).

**Shipment and Transfer of Biological Agents**

It should be noted by the results of this comparison that in contrast to the U.S. BMBL and the WHO LBM, the SRs consider in detail not only questions of shipment and transfer of biological materials but also registration and storage procedures for Hazard Groups I-IV pathogens including collections of cultures of microorganisms.

Documents regulating some important aspects of these activities obligatorily observed in the territory of Russia are presented as separate independent appendices to the Sanitary Rules: registration forms (18 forms); a list of causative agents of human, plant, and animal diseases (pathogens), their genetically modified forms, fragments of genetic materials, and equipment that could be used to develop biological and toxin weapons which are exported according to licenses (cited from the President’s decree); a document on the control of procedures for exporting causative agents of human, plant, and animal diseases (pathogens), their genetically modified forms, fragments of genetic materials, and equipment that could be used in the development of biological and toxin weapons; a classification of microorganisms that are pathogenic for man; a list of organizations possessing specialized collections Hazard Groups I-IV microorganisms; a certificate permitting shipment of special cargo (pathogens of Hazard Groups I-IV). In contrast to the U.S. BMBL and the WHO LBM, according to the Russian SRs, pathogens of Hazard Groups I-II are transferred and delivered within the country only by two special messengers. Pathogens of Hazard Groups I-IV are transferred abroad through the International Post Office. Figure 3 shows the packing, shipment, and transfer of pathogens of Hazard Groups I-IV within the country (metal containers of different sizes and shapes are used as secondary containers; wooden boxes or standard parcel boxes can be used as outer containers) (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993). The packing intended for shipment and transfer of pathogens of Hazard Groups I-IV abroad should satisfy international conventions and rules (Figure 3).

**Contingency Plans and Emergency Procedures**

A comparison of contingency plans and emergency procedures revealed that in contrast to the U.S. BMBL, the SRs and the WHO LBM contain a more detailed description of contingency plans and practical recommendations for emergency situations involving biological material. This makes it easier to further develop appropriate working instructions for microbiological laboratories. In addition, it is important, in our opinion, that the SRs contain a standard requirement for an isolation ward at any institution where work with causative agents of plague, cholera, glanders, melioidosis, deep mycoses, and highly contagious viruses of Hazard Group I are conducted. The availability of a specialized isolation ward provides injured individuals with qualified and specialized medical aid within the first hours after an incident (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993).

**Risk Assessment**

In contrast to the SRs and the WHO LBM, the U.S. BMBL contains scientific and methodical recommendations to correctly determine appropriate
biosafety levels when working with infectious agents using risk assessment procedures. Determination of a biosafety level is based on an evaluation of the facility, equipment, and procedures used during work with an agent(s). Neither the SRs nor the WHO LBM contains such a separate section. However, some microbiological laboratory activities involving high risks are mentioned in the SRs; these include centrifugation, lyophilization, work in aerosols chambers, and work with animals requiring special safety measures. The WHO LBM contains more detailed descriptions of safe laboratory techniques and procedures associated with various risks such as the generation of microbial aerosols. It should be noted that the selection of the biosafety level according to the SRs is strictly determined by the degree of danger when handling the infectious agent. The placement of this agent in the classification of pathogenic microorganisms was determined by leading microbiologists, epidemiologists, and the State Sanitary Inspection organs of Russia through a comprehensive analysis of all of the properties and characteristics of the agent (as in the case of a complex of risk factors) including interaction of the agent with the host. That is why the biosafety level required to work with a certain microorganism is determined by its placement in each hazard group of the microorganism classification presented in the SRs. The SRs and this classification are revised periodically (every 5 years) using newly obtained scientific and practical knowledge. It should be noted that many sanitary rules are the basis of Russian laws in the fields of
social security, health service, ecology, etc. The latter fact should be obligatorily taken into account when planning and carrying out activities on harmonization and unification of national biosafety guidelines, as it will certainly slow down this process (SRs 1994, 1999, 1996; CDC-NIH, 1999; WHO, 1993).

Primary and Secondary Containment Barriers

In contrast to the SRs and the WHO LBM, in the U.S. BMBL the concept of primary and secondary containment barriers is introduced from scientific literature, while the SRs and the WHO LBM contain only some hints on the use of different devices to protect personnel and the environment. In contrast to the SRs, the U.S. BMBL and the WHO LMB describe detailed characteristics and uses of different classes of biosafety cabinets and other equipment (engineering controls). It would be expedient to supplement the SRs with this information, taking into account the ever-growing use of engineering controls in Russian microbiological laboratories (SRs 1994, 1999; CDC-NIH, 1999; WHO, 1993).

Organizational Training

In all the analyzed documents, little attention was paid to the necessity of training personnel in the rules of working safely in microbiological and medicobiological laboratories. Only the WHO LBM contains special sections on personnel training and educational information. Surely the presence of analogous sections in the SRs would enhance their practical value.

Summary

The described differences among the Russian SRs, the U.S. BMBL, and the WHO LBM reflect national peculiarities in working with Hazard Groups I-IV microorganisms. These developed in each country or group of countries (e.g., European countries) over time and during the evolution of safe work practices with infectious microorganisms. These guidelines are not antagonistic to each other in principle. Each of these documents has its strengths and weaknesses. In an effort to harmonize and improve the guidance provided for working safely with these microorganisms, the authors of these documents may wish to consider revising their current documents to include information (e.g., field safety, risk assessment, training requirements, etc.) from other guidance documents. Organization and management of a project of this magnitude might be considered by the American Biological Safety Association International Working Group.

References


Revisions to the National Sanitation Foundation International/American National Standards Institute Requirements

David S. Phillips
ENV Services, Inc., Colmar, Pennsylvania

Abstract

Recent revisions in the National Sanitation Foundation International/American National Standards Institute Requirements (49-2002) for field certification of Class II biosafety cabinets are described, along with recommendations for end-users as to how to meet these modified standards.

Introduction

In March 2002, the National Sanitation Foundation International (NSF) completed an extensive revision of its Standard 49, which addresses the design, construction, and performance of Class II biosafety cabinets (BSC). The modified Standard contains significant changes in the test procedures and acceptance criteria for Field Certification. These revisions are retroactive in nature, applying to old and new Class II BSCs.

The following six containment tests are required for a cabinet to earn “Field Certified in Accordance with NSF 49”:
1. Downflow velocity profile
2. Inflow velocity
3. Airflow smoke patterns
4. HEPA filter leak
5. Cabinet integrity (type A1 only)
6. Site installation assessment

The revisions in the HEPA filter leak, the cabinet integrity, and the site installation assessment tests are the ones most likely to have an impact on current users and are the subject of this brief report. The minor changes in the other three tests are relatively transparent. For example, the uniformity requirement for downflow velocities has been expanded from 20% to 25% using the same test method. Therefore, the only changes in this test concern data analysis and a less restrictive acceptance criterion.

HEPA Filter Leak Test

Although the test itself remains unchanged, the maximum allowable patch restriction has been reduced. While the previous Standard allowed up to 5% of the HEPA filter area to be obstructed by patching, the revised NSF/American National Standards Institute (ANSI) 49-2002 Standard permits only a 3% maximum filter obstruction. The replacement of the HEPA filter is the only available remedy for units in which the extent of patching exceeds this new standard.

Cabinet Integrity Test

Class II, Type A1 BSCs (formerly Class II, Type A) is one of the least common Class II BSCs and the only one requiring an integrity test when it is installed or moved, and/or when the containment
panels are removed or replaced (e.g., upon replacement of filters or if repaired in a contaminated space).

The test, which requires no more than an hour to complete, involves sealing the cabinet with tape, plastic, and blank off panels. It is then pressurized to 2 inches w.g. and a soap solution applied to all welds, gaskets, penetrations, and seals. Leaks will be audible or indicated by bubbles and may be easily repaired by tightening panels.

**Site Installation Tests**

The assessment of the BSC’s installation represents an entirely new category of containment test and is designed to evaluate its operation when in actual use. The following are the four site installation tests which must be performed:

**Sash Alarm Function**

When the sash is raised 1 inch above the manufacturer's recommended height, an audible alarm must sound.

**Exhaust Alarm Function**

There are two types of cabinet exhausts—direct connection and exhaust canopy. The former represents a solid connection between the BSC exhaust opening and the building's dedicated BSC exhaust system. It is recommended that this dedicated system have constant flow rates, local flow adjustments (i.e., damper adjustments in the rooms), test ports for exhaust velocity measurements, and filter leak testing, as well as flexible connections or gas-tight dampers to facilitate an airtight seal for gas decontamination.

An exhaust canopy is a flared canopy, usually about 1 inch above the BSC exhaust opening. The canopy captures all of the exhaust flow coming from the biosafety cabinet and is recommended for all Type A1 and A2 (formerly A and B3, respectively) BSCs when external exhaust is desired. Many manufacturers can provide exhaust canopies and transitions designed to work with their biosafety cabinets.

The NSF/ANSI 49-2002 Standard requires that externally exhausted Class II BSCs have audible and visual alarms which are initiated within 15 seconds of a 20% decrease in exhaust air volume.

**Blower Interlock Function**

Class II, Type B2 BSCs (commonly referred to as “Total Exhaust” units) are required to have an alarm interlock that shuts off power to the supply blowers when the exhaust alarm is activated.

**Exhaust System Performance**

The revised Standard requires that no smoke escape the exhaust canopy once drawn in through the gap from the cabinet. Alternatively, the exhaust duct for BSCs that are exhausted through a direct connection must be negatively pressurized relative to the room.

**Conclusion**

The revisions contained in the NSF/ANSI 49-2002 Standard enhance the criteria for field certification of NSF listed Class II BSCs. As a result, cabinets certified under the old Standard may be required to undergo repair or, at an extreme, to be discarded as being incapable of meeting the new requirements. If the BSC is not NSF listed, then the issues relative to the new Standard would appear not to apply, as the cabinet was not designed to meet NSF criteria.

Capsule

Ed Krisiunas

WNWN International, Burlington, Connecticut

What's new, what's hot, what's timely? If you don't have time to search the Internet for the latest developments that might have an impact on your work environment, chances are you just might find some of this information in this "Capsule" column. Please e-mail any comments or suggestions to ekrisiunas@aol.com or to the Editor, Ira F. Salkin, at irasalkin@aol.com.

SARS

Issues related to Severe Acute Respiratory Syndrome (SARS) are being addressed in another portion of the journal this month. Many useful links can be found at the CDC web site. A recent piece on use of respirators is provided below.

Interim Domestic Guidance on the Use of Respirators to Prevent Transmission of SARS

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) have impacted many types of healthcare providers. The following web sites are good primers:
- http://aspe.hhs.gov/admsimp/
(a white paper "what is HIPPA")

"End of Polio" Web Site's Photo Essay Chronicles the Eradication of the Long-Prevalent Disease

Early in 2001, Brazilian photojournalist Sebastiao Salgado began documenting the global effort to eradicate polio. Inspired to be a witness to the end of a disease whose recorded evidence can be traced to 1580 BC, Salgado traveled to Somalia, Sudan, India, the Democratic Republic of Congo, and Pakistan to create a photographic record of the last of the mass campaigns against polio. His beautifully composed black-and-white photographs are featured on the "End of Polio" web site, along with explanatory text. To access the site, go to: http://www.endofpolio.org.

Begun in 1988, the Global Polio Eradication Initiative has helped cut the global toll of polio paralysis from an estimated 350,000 per year to 1,925 in 2002. The goal for 2005 is global eradication certification.

EPA Registered Disinfectants and Sterilizers

Last year there was a comment on BIOSAFETY about where the EPA listing of registered disinfectants and sterilizers would be published when the National Antimicrobial Information Network discontinued listing the information. After some digging I found the following site on EPA's web site that appears to be current. http://www.epa.gov/oppad001/chemregindex.htm.

Computer Staffing Model for Bioterrorism Response

A new computer model is available to help hospitals and health systems plan antibiotic dispensing
and vaccination campaigns to respond to bioterrorism or large-scale natural disease outbreaks. The model was funded by the Agency for Healthcare Research and Quality (AHRQ) and developed by researchers at Weill Medical College of Cornell University after testing a variety of patient triage and drug-dispensing plans. This project is part of a larger initiative of the U.S. Department of Health and Human Services to develop public health programs to address bioterrorism concerns.

This new resource is the nation's first computerized staffing model that is downloadable as a spreadsheet or accessible as a Web-based version. It can be used to calculate the specific needs of local health care systems based on the number of staff they have and the number of patients they would need to treat quickly in a bioterrorism event. The new computer model allows health care system planners to estimate the number and type of staff required to operate these clinics in order to provide an entire community with critical medical supplies in an efficient and timely fashion. The model can be downloaded to run on common spreadsheet software and customized for use by health officials at all levels of government, hospital administration, and emergency medical planning.

To download the Mass Prophylaxis/Vaccination Campaign Staffing Model, go to: http://www.ahrq.gov/research/biomodel/index.asp.

Copyright Constraints

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For Technical Assistance

Permission requests and technical assistance questions on the use of the model should be directed to:

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For Additional Information

If you have any questions about AHRQ's bioterrorism and health system preparedness program, contact:

Dr. Sally Phillips
Director, Bioterrorism Preparedness Research Program
Center for Primary Care Research
Phone: 301-427-1571
E-mail: SPhillip@ahrq.gov
(current as of June 2003)

Internet Citation

Ask the Experts—Biosafety Requirements for Human Cell Lines

John H. Keene
Biohaztec Associates, Midlothian, Virginia

Do you have a biosafety question and you’re not sure whom to ask? Send your questions to the “Ask the Experts” column and I’ll get them answered for you. Drawing from my own experience or that of other experts in the field, we’ll try to compile a thorough and comprehensive answer to your question. Please e-mail your questions to jkeene@biohaztec.com or to the Editor, Ira F. Salkin, at irasalkin@aol.com.

Biosafety Requirements for Human Cell Lines

As I was contemplating my article for this issue of Applied Biosafety, the topic of biosafety requirements for “human cell lines” popped up on the Biosafety Discussion List. It seems that we biosafety professionals have not done a very good job, in some instances, of explaining the differences between Biosafety Level 1 and Biosafety Level 2 practices to our researchers, and it is very important that we provide this most basic level of instruction. I hear over and over that a particular researcher feels that the imposition of Biosafety Level 2 practices is somehow going to interfere with his or her work and slow down or inhibit being able to perform research in an efficient manner. We often attempt to blame the Occupational Safety and Health Administration (OSHA) or some other regulating body for the requirements, and then the researchers comment that the requirement is “stupid” or has no “scientific basis.” It seems to me that we ought to put this problem to rest once and for all.

First, with regard to the inclusion of “human cell lines” under the Bloodborne Pathogens Standard (BPS), OSHA provided the following interpretation to Dr. Diane Fleming, ABSA President, on June 21, 1994. The letter is available on the OSHA web site at: (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519).

Dear Dr. Fleming:

This is in response to a September 23, 1993 letter from Joseph H. Coggin, an American Biological Safety Association member, requesting clarification of our August 3, 1993 letter of interpretation to the former ABSA President Dr. Jerome P. Schmidt. That letter attempted to explain the applicability of the Occupational Safety and Health Administration’s (OSHA) standard 29 CFR 1910.1030, “Occupational Exposure to Bloodborne Pathogens,” to establish human cell lines.

Dr. Coggin informed us that our August 3, 1993 letter may be more confusing rather than enlightening to biological safety professionals.

We have reconsidered our earlier comments and are providing a more detailed letter of interpretation. We regret any misunderstanding our earlier response may have caused.

As you know, the Bloodborne Pathogens standard (BPS) provides protection to employees who have occupational exposure to human blood or other potentially infectious materials (OPIM). Established human cell lines* (see attachment) which are characterized** (see attachment) to be free of contamination from human hepatitis viruses, human immunodeficiency viruses, and other recognized
bloodborne pathogens, are not considered to be OPIM and are not covered by BPS. Established human or other animal cell lines which are known to be or likely infected/contaminated with human microbes or agents classed as bloodborne pathogens, especially hepatitis viruses and human immunodeficiency viruses are covered by the BPS. The final judgment for making the determination that human or other animal cell lines in culture are free of bloodborne pathogens must be made by a Biosafety Professional or other qualified scientist with the background and experience to review such potential contamination and risk, in accordance with the requirements of the BPS. Documentation that such cell lines are not OPIM should be a matter of written record and on file with the employer for OSHA review.

All primary human cell explants from tissues and subsequent in vitro passages of human tissue explant cultures (human cell "strains"**, see attachment) must be regarded as containing potential bloodborne pathogens and should be handled in accordance with the BPS. Non-transformed, human cell "strains," characterized by documented, reasonable laboratory testing as described in the attachment, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must be handled in accordance with the precautions noted in the BPS. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the BPS.

All laboratory work with primary human tissues or body fluids is covered by the BPS.

We hope this information is responsive to your concerns and thank you for your interest in worker safety and health.

Sincerely,

Ruth E. McCully, Director
Office of Health Compliance Assistance

**Definitions

*A Human Cell LINE is defined as in vitro or animal passaged (e.g., nude mouse) cultures or human cells that fulfill traditional requirements of a cell line designation. That is, the cells are immortalized cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalizing agent such as Epstein-Barr virus (EBV). EBV is a bloodborne pathogen. It should be noted that human cervical carcinoma cells or other transformed human cell lines like HeLa cells are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human HeLa cells, without having to comply with the requirements of the bloodborne pathogens standard (BPS), human HeLa cells should be documented to be pure HeLa cells and shown to be free of bloodborne pathogens by testing.

**Characterization of human cells, for inclusion or exclusion from compliance with the BPS, would include screening of the cells lines or "strains" for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses or EBV, if the cells are capable of propagating such viruses. Most cell lines are screened for human mycoplasmas and are free of bacterial and mycotic contaminants. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology (polymerase chain reaction or nucleic acid hybridization) to identify latent viruses capable of infecting humans such as Herpesviruses (e.g., EBV), or papilloma members of the Papovavirus group, etc. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the BPS.

***Human cell STRAINS are defined as cells propagated in vitro from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards unless characterized by testing to be free of bloodborne pathogens (i.e., WI-38 cells are often so documented).

This is pretty straightforward and is now available for all to read and keep on your desk to answer
any questions from your researchers. There is no question of “stupidity” or “scientific validity”; this is the interpretation of the law and failure to follow the law can result in serious consequences to the institution.

A second source of information on human cell lines that should be considered is provided by the American Type Culture Collection (ATCC) in their web site’s Frequently Asked Questions section (http://www.atcc.org/TechnicalInfo/faqCellBiology.cfm#Q53).

This resource is reprinted with permission from the American Type Culture Collection.

“Are ATCC human cell lines tested for viruses such as Epstein-Barr (EBV) virus, human immunodeficiency virus (HIV, AIDS virus), human T cell leukemia (HTLV), and hepatitis B virus? Are ATCC cell lines tested for bovine viral diarrhea virus (BVDV)?”

Answer: Some of our human cell lines are known to produce EBV, HTLV, or hepatitis, and this information is given in the catalog description and on product sheets. In addition, the human lung cell lines in our CCL collection have been screened and found negative for viruses by procedures that are detailed in our quality control manual (egg inoculation, hemadsorption, and co-cultivation with indicator cells). At this time, ATCC is distributing the HIV-positive line H9/HTLV-IIIB (ATCC CRL-8543). However, some of our other patent deposits have been derived from AIDS patients and may carry HIV.

Since it is not possible for us to test every cell line for every possible virus, we rely on the tests performed by the depositor. We recommend that all human cell lines be accorded the same level of biosafety consideration as a line known to carry HIV.” (Underlining added by the author for emphasis.) “With infectious virus assays or viral antigen assays, even a negative test result may leave open the possible existence of a latent viral genome. Thus, it is best to use caution when handling any human cell line. Concerning BVDV, the virus is present in most serum samples, often at very low levels. Hence, it is probably present in all cell lines in which it can replicate unless the cultures have been grown in rigidly tested sera or sera of non-bovine origins. A paper describing testing of some ATCC lines was published in 1994 [S. R. Bolin et al., (1994) Survey of cell lines in the American Type Culture Collection for bovine viral diarrhea virus. J. Virol. Methods 48, 211]. Lines that are positive for BVDV are so described in the ATCC catalog descriptions.”

Here it is very clearly stated that it is impossible to prove the negative. How do you know a pathogen is not present when you might not know that the pathogen even exists, until it shows up as a causative agent of a new disease? If you think this can’t happen, consider the HIV epidemic.

If we assume that the law requires us to prove that a material does not have infectious agents in it and to follow Biosafety Level (BSL)-2 procedures in a BSL-2 laboratory, how do we convince our reluctant researchers that we are not causing them to do something that will interfere in some way with their research? Look at the requirements for BSL-2 procedures and tell me if there is anything in these procedures that we really should not be doing. Following these Good Microbiological Procedures is important for the protection of the research as well as the personnel. These are the procedures, which are used in every clinical microbiological laboratory in the country and elsewhere. One does not have to have a PhD in microbiology to easily and efficiently follow these requirements. In fact, following them is good microbiological research. I encourage each biosafety professional to respond to the researchers who are concerned about the “hardships” of BSL-2 requirements by pointing out that the researcher is probably already following most of the BSL-2 requirements in a laboratory that would qualify as a BSL-2 laboratory.

It is the Law. Help them to understand that with little extra exertion, they can be compliant and reduce the potential for contamination of their research and themselves.
Biosafety Tips

Karen B. Byers
Dana Farber Cancer Institute, Boston, Massachusetts

Biosafety Tips brings you practical approaches to biosafety or "news you can use." If you are looking for a useful and sensible solution to a biocontainment problem or perhaps a reference to help convince a skeptical researcher of the need for caution, this is the place to look. In this column I will share some biosafety insights for managing a variety of situations that arise in the workplace. I welcome feedback or suggestions for future topics. Please send them by e-mail to karen_byers@dfci.harvard.edu or to the Editor, Ira F. Salkin, at irasalkin@aol.com.

I have found that using reports of actual laboratory incidents as part of training programs can help pique audience interest and motivate lab staff to incorporate good microbiological practices into their daily routine. In this issue's Biosafety Tips, I've provided citations and descriptions of some recent laboratory-acquired infections which may be useful in your safety training sessions.

Case I


A laboratory worker sustained a needlestick while conducting a viral purification procedure using cells infected with vaccinia virus (strain WR). Although the individual had been vaccinated against smallpox in childhood, a pustule appeared on her thumb 3 days after the injury. By days 5 and 6 post-needlestick, new pustules appeared on the worker's fourth and fifth fingers and she developed axillary lymphadenopathy. On day 8 after the incident, a large erythematous patch developed on her forearm and tissues around the finger lesions became necrotic. On day 9, the lesions worsened and antibiotics (amoxicillin/clavulanate) were prescribed due to the suspicion of secondary bacterial infection. The necrotic tissues on the hand lesions were surgically excised. Gram stains on the pustular fluid from the lesions were negative, but diluted pustular fluid inoculated into BSC-40 (monkey kidney) cell cultures produced poxlike cytopathic effects. Virus recovered from the lesions was analyzed with Western blot and polymerase chain reaction (PCR)—restriction length polymorphism and was found to be identical to the strain used in the laboratory. The patient made a full recovery 4 weeks after the initial injury.

The authors state that their "study supports the need for vaccination for laboratory workers that routinely handle orthopoxvirus."

Further guidance and thoughts for training workers:
- The images in Figure 1 in this online paper may convince researchers working with virulent strains of vaccinia to get immunized.
- The following document lists various vaccinia strains commonly used in laboratories and provides specific vaccination recommendations: Vaccinia (smallpox) vaccine recommendations of the advisory committee on immunization practices (ACIP), 2001, MMWR, Vol. 50, No RR10;1 (6/22/2001) available is online at URL: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm.
Case II


Here is another cautionary tale in which the authors report a vaccinia virus infection in a laboratory staff member following laboratory exposure to a genetically modified vaccinia virus strain. The worker had been vaccinated during childhood and had no personal history of atopy or chronic skin disease. While he was unaware of any accidental injury or exposure incident, he did have a “mild skin barrier disturbance from working with unprotected hands in cold temperature over a prolonged period.” This staff member processed vaccinia cell cultures with high concentrations of recombinant virus (10^9 plaque forming units [PFU]/ml). He noticed a vesicular lesion on the second finger of his right hand which slowly progressed to become a 15 mm infiltrated, inflammatory nodule with central hemorrhagic necrosis. A second inflamed lesion developed 2 days later on the third finger of the left hand. After unsuccessful surgical therapy, a skin biopsy and serum samples were taken. The lesions were treated with topical disinfectants and healed completed in 2 weeks.

The skin biopsy sample was split to allow its analysis by electron microscopy, as well as to inoculate cell cultures. Electron microscopy observation of the tissue sample revealed a poxvirus. The tissue culture yielded a poxvirus, which was subsequently studied by PCR, digest electrophoresis, and sequence analysis. The isolate was identified as the Western Reserve strain of vaccinia virus, genetically modified to contain a functionally inactivated cytokeratin-1 gene of human origin—the same recombinant virus used in the laboratory. The gene in this recombinant virus has been shown to impair leukocyte adhesion.

This report could illustrate that:
- Genetic modification does not necessarily make the virus less virulent; careful consideration must be given to the potential effects of each insert.
- Vaccinations received at infancy and again 28 years prior to this infection were not fully protective.

Case III


A 25-year-old laboratory technician who had not been previously vaccinated cut her finger on a coverslip. Since a lesion did not develop at that site until 12 days postinjury, the authors assumed that the cut itself was not an exposure incident. They reasoned that the cut site must have been contaminated with the virus at a later time. Unfortunately, the staff member squeezed the “pimple” which developed at the cut site and pus squirted onto her chin. Two days later, a lesion developed on the chin, and she was diagnosed with generalized vaccinia. Thirty-six days later, she felt “almost back to full strength, despite the blackened eschar on her finger.” Electron microscopic studies confirmed the presence of pox virus in the lesions.

**Conclusions:**
- The authors concluded that staff “should be educated about the potential hazards of the work environment, including autoinoculation and the potential spread to contacts.”
- Staff must seriously consider the potential risks of the organisms with which they work.
- The authors also advised compliance with the CDC recommendation of smallpox vaccination within the previous 10 years for staff handling the Western Reserve strain of vaccinia.

*Full bibliographic information is not yet available for this citation; it is listed on ScienceDirect.com as an “Article in Press.” The Digital Object Identifier (DOI number) is assigned by the publisher upon initial electronic publication.*

Case IV


A 40-year-old microbiologist worked in a bacteriological laboratory processing wound swabs from
which he routinely isolated strains of methicillin-resistant *Staphylococcus aureus* (MRSA) and EMRSA-15 (endemic MSRA) daily. At one point, he had an upper respiratory infection which caused him to blow his nose in a handkerchief while handling plates and doing the slide coagulase test on the bench. Sometime later, he went out bushwacking in Australia and cut his leg on a plant. This cut became infected and MRSA (EMRSA-15) was isolated from it. The person had no risk factor for MRSA (no chronic illness, injecting drug use, direct contact with patients) other than working with the organisms. Several weeks after remission of the leg infection, EMRSA-15 was isolated from a nasal swab recovered from the individual. This isolate was indistinguishable from the one isolated from his leg wound. The authors plan to study colonization of laboratory workers with MRSA.

*Staphylococcus aureus* is normally transmitted by direct skin contact or fomites; however, the authors assume that the transmission and subsequent nasal colonization occurred when the scientist, without prior hand washing, blew his nose while working with MRSA strains.

Topics for discussion:

- The authors advise thorough hand washing to prevent transmission; there is no discussion of whether gloves were routinely worn during these procedures.
- Nasal colonization is always a concern when working with MRSA strains, especially when there are breaks in hygiene.
- This example is particularly useful if workers neglect to wear gloves to handle potentially contaminated plates or fail to wash their hands after glove removal.

Case V


In the UK, strains of *Brucella* isolated from marine mammals are studied in a BSL3 containment laboratory. Blood tests of one researcher who developed continuing headaches, lassitude, and severe sinusitis indicated positive titers against *Brucella* that rose during the course of the infection. The strain of *Brucella* isolated from the researcher’s blood had been previously isolated only from sea mammals.

Although antibiotics relieved the clinical symptoms in a week, a full 6-week course of treatment with doxycline and rifampicin was completed. The staff member remains symptom-free but seropositive. No other staff members seroconverted. All work was done in a Class III cabinet and, according to the author, “despite a detailed investigation by an independent authority” no specific problem was identified with its operation. The author cites an unpublished study indicating that 27% of stranded sea mammals were seropositive for *Brucella*, and reminds us of the zoonotic potential of sea mammals.

You might use this example to illustrate:

- Probable aerosol exposure
- Laboratory-acquired infections can occur in the absence of a specific exposure incident
- Zoonotic infections from marine mammals

Case VI


*Vibrio parahaemolyticus* is an important cause of bacterial food-poisoning outbreaks in Taiwan and had been previously isolated from abalones. In this study, a V. *parahaemolyticus* isolate (designated 880713) recovered from a human stool sample during a probable foodborne infection was injected into abalones to determine its virulence in this animal model. The laboratory also isolated V. *parahaemolyticus* (isolated 880915) from the hemolymph of a diseased small abalone and injected it into another set of abalones. The animals were kept in laboratory aquaria and observed daily. Moribund animals were removed by a lab member and samples were obtained for isolation and identification of bacteria. After the experiment had been set up, an earthquake occurred in Taiwan and the laboratory did not have water or electricity for a week. As a result, the authors state that “the usual higher standards of hygiene could not be maintained.” However, work on
this project apparently continued and the lab member who removed moribund abalones from the aquaria suffered two episodes of acute gastritis during the week of the utility outage. Both strains of *V. parahaemolyticus* 880915 and 880713 were isolated from the lab worker’s stool samples. This is the first recorded instance of infection of abalones with a human isolate of *V. parahaemolyticus* and the first laboratory-acquired infection from laboratory-infected abalones.

This report could be used to emphasize the following points:
- That hand washing is important, even though the use of gloves was not discussed in this publication
- Disaster planning should address safety procedures for the staff to follow.
- A new animal model may be a new source of zoonosis.
ABSA Biosecurity Position Paper

Barbara Johnson
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Introduction

Since June 2002 Public Law 107-188 and several Codes of Federal Regulation have been codified in the US to promulgate increased biological security and safeguards at facilities working with, storing, or transporting pathogens and biologically derived toxins. Other countries are currently examining their policies and procedures regarding the safeguarding of certain pathogens and biological toxins. The objective of Public Law 107-188, the Public Health Security and Bioterrorism Response Act of 2002, is to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. The intent of the attendant CFRs addresses a subset of PL 107-188 and focuses on preventing individuals from gaining access to certain biological materials and using them for illicit purposes.

Pathogens increasingly traverse countries via innocuous or unknown reservoirs, infected individuals, and vectors. These novel, and in some cases re-emerging diseases, pose a collective risk to international health, stability, and national/international security. Public health initiatives such as the development of networks of international reference laboratories whose goal is to facilitate global recognition, reporting, and response to emerging health threats will become an increasingly vital component of world biological security and health.

ABSA believes it is important to recognize the importance of balancing programs that promote global public health initiatives with the need to implement biosecurity requirements intended at preventing potential proliferants from gaining access to sensitive biological materials.

Statement of the Problem

Decades ago, governments defined and established programs to address the security of nuclear materials, chemical stockpiles, and associated weapons. The programs were often conducted at facilities that were closed to the general public and relied heavily on the "guards, gates, guns, and two-man rule" approach to security and personnel reliability. This paradigm does not optimally meet the needs of security in biological facilities and may actually cause a false sense of security, while causing significant damage to academia, research, public health, and the biomedical and biotechnology industry. This does not mean there is no need for biosecurity; rather, that a security approach must (1) understand the unique aspects of biological work and materials; (2) identify the assets and vulnerabilities associated with biological programs; and (3) develop measures that address and solve the problem.

Why Biological Materials Pose Unique Challenges

Several aspects intrinsic to work with biological materials have been identified as key drivers for biosecurity to be implemented differently than other security programs. First, biological pathogens can replicate, making the theft of even minute quantities significant. Access control and mechanisms for monitoring access may deter the average unauthorized individual from entering an area and gaining possession of pathogens from working cultures, stocks, infected animals or bedding, and laboratory freezers or refrigerators.
However, it does not address the threat of an authorized individual from obtaining pathogens for illicit use. It is vital that individuals working with, or with access to, pathogens be responsible, reliable, well trained, and trustworthy. ABSA believes that personnel reliability is a cornerstone of biosecurity, and identifying appropriate measures directed at vetting individuals with access to these agents is part of the path forward in implementing a viable biosecurity program.

The second aspect is that there are no devices that detect biological pathogens or toxins being taken from a facility, and existing “tag and detection” technology can be defeated in a number of ways. While random searches of personal belongings may deter some individuals, the minute amounts required can be transported in a number of matrices and never be detected. Again, individual integrity is of paramount importance.

Finally, pathogens deemed as those of “high consequence” and toxins can be found in existent clinical laboratories, research universities, private industry, and numerous government R&D programs. These agents often persist endemically and are responsible for natural outbreaks of disease in many countries.

ABSA believes analyses of new or proposed biosecurity rules should be conducted to determine whether they actually provide increased biosecurity or merely foster the perception of increased security. A relevant example brings to question whether in light of the current availability of these materials, developing more restrictive export rules or enacting an export moratorium, will actually facilitate biosecurity, give the perception of securing materials, or substantially deter future legitimate research and public health endeavors.

**Approach to Developing a Biosecurity Program**

Several components that form the cornerstones in the development of a biosecurity program include: concept of security management; security plan development; security risk analysis; and assessment of proactive and reactive measures. Security management is a systematic process designed to develop a rational and cost-effective biosecurity program strategy that will protect critical facility and programmatic assets. Security plan development would optimally be a coordinated effort between major stakeholders (i.e., security, biosafety, scientific director, local law enforcement, others). The risk analysis process develops assessments of assets, threats, vulnerabilities, and risk that will then be reviewed in the context of countermeasure applicability. Countermeasures are plans, actions, technologies, or other measures that are taken to prevent, lessen, or respond to a threat. Countermeasures are broadly based on personnel, technical, and operational considerations and solutions. The biosecurity program should at a minimum address the following elements: physical protection; personnel suitability/reliability; pathogen accountability (onsite and through the transportation process); and biosecurity incident response.

**Proactive Measures to Implement a Biosecurity Program**

Measures should be chosen to fulfill identified functional requirements with consideration to mission objectives, goals, and other operating constraints. Institutes, their biosecurity requirements, and approaches to meeting those requirements may vary. Some applied requirements identified by a broad range of facilities may include general aspects of managed access to include visitor control, location of biological materials within a facility and access to biological materials, and material accountability. Approaches should include the development of written and documented security procedures and would optimally provide funding for a designated site security administrator (and trained security staff) to ensure compliance and consistency in implementation. As one commonality across facilities is that personnel are key assets, a combined approach of (1) hiring practices that select for honest, well-balanced employees; (2) establishing a personnel reliability/suitability program; (3) establishing an effective Employee Assistance Program; and (4) raising the level of security awareness among employees may be
among the most important factors in developing an effective biosecurity program.

Conclusion

As a discipline, biosecurity has been evolving at institutes and across various agencies and industries in an independent manner. ABSA believes it would be beneficial for member states to develop national guidelines or a set of recommendations for biosecurity in facilities working with, storing, and transporting pathogens. It will be incumbent upon member states to implement and enforce these guidelines. A proponent organization that develops these guidelines will have to intimately understand the intricacies and unique aspects of pathogens and work with pathogens. ABSA advocates a unified approach by member states in developing international recommendations and standards. ABSA believes BTWC member states should involve experts from professional associations, such as ABSA, to provide comment on technical aspects of evolving text and new requirements.

Respectfully submitted,

Barbara Johnson

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17 July 2003
ABSA Committee Reports

The following information was provided by the chairs of the indicated committees to keep members abreast of their activities.

Communications Committee

Melina Kinsey, BS, RBP, Chair
Midwest Research Institute of Florida
Palm Bay, Florida

Since the launch of the new ABSA web site on December 11, 2002, the Communications Committee has been busy updating and enhancing the web site at the request of the membership and ABSA committees. We are still on target to implement a Members Only section by October 2003 which will include a registry of ABSA expertise and speaker’s bureau developed by the Technical Resources Committee. The Communication Committee’s objective is the promotion and continued development and oversight of the ABSA web site (www.absa.org) in order that it remains the fundamental means of transmitting and receiving information for the membership. To fulfill this goal the Communication Committee is in need of volunteers to serve as communication liaisons to educate and promote the strengths of our web site with the other ABSA committees. When you choose to serve on a volunteer committee, you open up a world of possibilities for networking, professional growth, and career opportunities while serving your profession. Volunteer member groups are the backbone of the ABSA.

Local Arrangements Committee

Harriet Izenberg, Chair
University of Pennsylvania
Philadelphia, Pennsylvania

The Philadelphia Local Arrangements Committee has been busy planning the 2003 conference. In addition to helping plan and present the first pre-conference course on molecular biology, the LAC has also worked with the Scientific Program Committee to provide speakers on SARS and other topics of interest. The committee has a few surprises in store—starting with a special welcome at the opening reception. This year, our special event will be held at the Franklin Institute, a grand neoclassical science museum founded in 1824. The Institute is located on the Benjamin Franklin Parkway, within walking distance of the hotel, for those interested in a pre- or postprandial stroll. In addition to food provided by Frog Commissary Catering, one of the city’s finest caterers, there will also be opportunity to network, dance, explore interactive museum exhibits, and enjoy an IMAX movie.

Philadelphia has been called the “City of Brotherly Love” and the “Place that Loves You Back.” Either way, it has much to offer. Historically, there is the Liberty Bell and Independence Hall, where the Declaration of Independence and the U.S. Constitution were created. Visit Elfreth’s Alley to get a glimpse of life in the days of our forefathers. Stroll or jog along the Benjamin Franklin Parkway and the river drives. Visit the Philadelphia Museum of Art, a short walk from our hotel, or take a carriage ride through the historical district.

Too lazy to walk? Ride the Ducks, Philly’s newest attraction, is a combination of land and water sightseeing fun. This 80 minute, fun-packed ride is both entertaining and informative, taking you through the city’s Historic District, South Street, and Society Hill. Then splash into the Delaware for a relaxing cruise—all on board one amazing vehicle.

And don’t forget to visit America’s First Zoo. The Philadelphia Zoo was founded in 1859. However, due to the Civil War, it opened its gates 15
years later on July 1, 1874.

If you are a foodie, Philly is the place for you. Everything from soft pretzels to cheesesteaks to five-star restaurants is at your fingertips! The LAC is busy as I write, preparing a list of their favorite dining spots for your enjoyment. And sports fanatics should not forget Philly sports teams, the Phillies, the Eagles and the Flyers...if you are in luck, there will be a game on while you are in town.

Thanks to the support of our sponsors (Novartis, Tier DE, the Baker Company, ENV Services, Merck, Aventis, Pfizer, and P&K Microbiology Services) and the hard work of the Training and Education and Scientific Program Committees, the 2003 Philly conference is shaping up into an event not to be missed. The LAC is available to answer any questions you may have before as well as during the conference—and we all look forward to seeing you there!

Marketing and Media Committee

Sandy Ellis, Chair
DUH2A
Atlanta, Georgia

During the past year, the ABSA Media and Marketing Committee has been working on a new brochure and new graphics for the portable exhibit. The new images and text will help ABSA attract new members worldwide and portray ABSA in a professional light. It is ABSA’s intent to utilize the booth and new brochures not only at the ABSA annual conference and affiliate meetings, but also at the conferences and meetings of similar organizations. During 2003, the existing booth traveled well to the BioSecurity Symposium in Alexandria, Virginia, the Tradelines Conference in Hilton Head, South Carolina, and the European Biological Safety Association Conference in Lyon, France.

The ABSA Media and Marketing Committee extends an open invitation for members to participate in attending the booth at any venue to help field questions from new and potential members with respect to membership rewards. As we are all aware, there is a wealth of knowledge to be gained at the conferences above and beyond the scheduled program, plus there are networking opportunities and the stimulus for a chance forum.

Special thanks from ABSA is extended to Lasha Orzechowski and Rick Sellar of Velocity Design Works, CUH2A/Smith Carter and Hemisphere Engineering, Inc. for their efforts and contributions towards the new brochures and new graphics for the portable exhibit. Additional gratitude is given to Health Canada for the donation of an ILC/Dover positive pressure suit which gives the portable exhibit an extra three-dimensional appeal.

Registration Evaluation Board

Richard Rebar, Chair
GlaxoSmithKline
King of Prussia, Pennsylvania

The purpose of the Registration Evaluation Board is to review applications for registration as a biological safety professional and determine if the applicant meets the established criteria. The board is composed of five members. The 2002-2003 committee members are Manuel Barbeito; Jack Keene; Betty Kupskay; Richard Rebar, Chair; and Don Vesley.

Summary of activity from February 2003-July 2003: 7 RBP applications received; 2 applications disapproved; 2 applications approved; and 3 applications pending.

The qualifications of the following individuals have been evaluated by the Registration Evaluation Review Board and based upon this review have been granted Registered Biosafety Professional (RBP) status by the American Biological Safety Association (ABSA). The following individuals are listed with their affiliation as of the approval date: Rene Aline Ricks—Registration number: 105, Health & Safety Consultant, April 8, 2003; and, Patricia L. Olinger—Registration number: 106, Pharmacia Corporation, May 12, 2003.

There are currently a total of 106 Registered Biological Safety Professionals. Please visit the ABSA web site (www.absa.org) to view application materials and criteria for becoming an RBP.
Scientific Program Committee

Karen B. Byers, MS, RBP, CBSP, Chair
Dana Farber Cancer Institute
Boston, Massachusetts

The Scientific Program Committee has developed an exciting program for the 2003 ABSA Conference in Philadelphia, Pennsylvania. Thirty-six excellent platform presentations will provide the latest information on a wide range of topics, including infectious agent research models, case studies and research on emergency preparedness, compliance with select agent regulations, occupational health and safety in the care of nonhuman primates, review and training associated with gene transfer protocols, innovative training techniques, developing and implementing biosecurity plans, biosecurity in the design process, containment laboratory design, critical biosafety program elements, evaluation of regulatory compliance (including lab audit by PCR), and decontamination. There will be plenty to discuss, both in the program hall and outside!

On Monday, a special poster session will allow ABSA members to grill the presenters on a wide range of topics. Examples include PERV, identification of select agents, community response to a biodefense lab, public health efforts to control plague, and decontamination. You’ll want to rest before you come to the conference because there are also five workshop/panel discussion formats planned. The Training and Education Committee has organized a workshop entitled “Implementation of the New Select Agent Regulation: Fine-tuning Your Program.” In addition, Lynn Harding, CBSP, organized a workshop on “The Open Laboratory Design Concept in 2003—How Well Does This Design Concept Work?” Furthermore, we are thrilled that three ABSA affiliates have organized and will present the following workshops of interest to biosafety professionals:

Improving Responses to Bioterrorism: Lessons Learned from the Anthrax Attacks. Robert Curtis, USDOL/OSHA, Salt Lake City, UT; John H. Bridges III, USPS, Washington, DC; David Ippolito, USDOL/OSHA, Washington, DC.


Compliance with the NIH Guidelines: Questions Answered by the NIH Office of Biotechnology (OBA). Allan C. Shipp, Director of Outreach, and Stephen Rose, PhD, OBA Deputy Director for the Recombinant DNA Program.

I haven’t even mentioned the exciting speakers who will present the Wedum and Eagleson Memorial Lectures, or the student presentation which won the Gross Memorial Award. This stimulating program for the ABSA conference was developed by the dedicated members of the SPC, who responded to innumerable e-mails, participated in several conference calls, and got us to this point. They are Andrew Braun, Maureen Best (Council Liaison), Karen Byers (Committee Chair), Nick Cirino, Barry Cohen, Serene Forte, Bob Hawley, Betty Kupskay, Andrea Maki, Michele McKinney, Pat Olinger, Rosamond Rutledge-Burns (Past Chair), Deanna Robbins, Ellyn Segal, Heather Sheely, Elizabeth Smith, Curt Speaker, Guido Vogel, and Ken Yu. See you in Philadelphia!

Training and Education Committee

Anne-Marie Bakker, MS, Chair
Berlex Biosciences
Richmond, California

It has been an exciting and busy year so far for the Training and Education Committee (T&E). Two new programs have been initiated (i.e., “Principles and Practices of Biosafety”): a 40-hour training course and the ABSA Summer Series. This fall the T&E Committee will be presenting 20 preconference and two postconference courses at the national conference in Philadelphia. In addition to the course offerings, the committee will also be facilitating a Roundtable on Select Agent Compliance. The committee will once again be selecting the “Outstanding Means of Communication Citation.”
Preconference Courses

The T&E Committee will be presenting 22 courses this year at the conference. Due to the large number of courses and the limited number of classrooms, two of the courses will be offered on Wednesday afternoon post conference. This is also an opportunity to evaluate this time slot as a viable alternative to only preconference courses. Course offerings are posted on the ABSA web site at www.ABSA.org.

Roundtable

This year the committee is coordinating the “Select Agents: Implementation of the New Regulation–Fine-tuning Your Program.” This roundtable will include a quick overview of the requirements. Representatives from public institutions and industry will discuss how they approached the implementation of the new regulations. This is an opportunity for you to compare your program with that of your colleagues and to discuss compliance issues with the speakers and the audience. Confirmed speakers include Stephen A Morse, CDC, providing a quick review of the requirements; Phillip Hauck, Mt. Sinai School of Medicine, talking about implementation of the program at a large institution; and Barbara Fox-Nellis, University of Florida, reviewing recent CDC & USDA facility inspections for their Select agent program. We are still looking for a representative from the USDA and industry interested in sharing his or her experience in implementing the new program.

2003 Training Exhibit and the ABSA 2003 Outstanding Means of Communication Citation

The T&E Committee encourages you to participate in the Training Exhibit display at the ABSA Conference (www.absa.org/confsem.html) by sharing your original biosafety materials, such as newsletters, booklets, manuals, training handouts, videos, and books authored by biosafety professionals. Web, CD-ROM, and other electronic training materials are also welcome.

The Outstanding Means of Communication Citation was developed by the ABSA T&E Committee in conjunction with the ABSA Awards Committee (www.absa.org/abocommittees.html) to formally acknowledge high-impact and original (noncommercial) training materials. Submitted items are judged for their effectiveness and creativity. All ABSA members are eligible for the Citation, which is presented at the ABSA Conference.

Principles and Practices of Biosafety

The inaugural presentation of the “Principles and Practices of Biosafety” course was conducted on June 15-19, 2003 at Berlex Biosciences in Richmond, California. The course was a sellout with 42 class participants. There were over 13 on the waiting list and many more interested in participating in next year’s class.

The course went very well. The participants were very complimentary and said that if they hadn’t known, they would have never thought that this was the first time the course had been presented. Also, all of the people who completed the overall evaluation form said that “YES,” they would recommend the course to others.

I want to thank LouAnn and her subcommittee for their 2 years of hard work to develop and present a top-notch course. The subcommittee is already hard at work going through the evaluations and planning the 2004 course. The plan is to have the 2004 course location and date announced at the national conference.

Our efforts were clearly very much appreciated by the participants, and I think we can expect continued success with this course.

ABSA Summer Seminar Series

The first annual summer series was conducted on July 16-17, 2003 in San Francisco with three courses offered. The courses included “Biosafety Level 3: Laboratory Operations and Facility Design Considerations,” taught by Dr. Robert Ellis; “Occupational Health Surveillance and Monitoring,” with Dr. Gary Fugimoto; and “Laboratory Incident Investigation and Risk Management,” with K. Patrick McKinney as the instructor. Over 73 people attended with many taking several of the courses. A special thanks goes to Michelle McKinney for her diligent work in making the seminar a reality. She was responsible for keeping the process moving forward and on track. The committee will be reviewing the evaluation forms and soliciting ideas for the 2004 summer seminar.
Fund Donations

Editorial Note

The following is a list of those who have generously contributed to the Richard C. Knudsen Memorial Fund. The proceeds from this fund will be used to establish an award to honor Rich’s memory. Those wishing to make donations to this fund should make their checks payable to the American Biological Safety Association. Please add a notation to the memo line that the check is to be used for the Richard C. Knudsen Memorial Fund. Checks should be mailed to ABSA, 1202 Allanson Road, Mundelein, Illinois 60060-3808.

Ira F. Salkin
Editor

Knudsen Fund Donations as of August 19, 2003—Total $13,968.53

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**October 17-20, 2004**
American Biological Safety Association (ABSA) 47th Annual Conference
Adams Mark Hotel, San Antonio, Texas
*Contact:* Phone: 847-949-1517, Fax: 847-566-4580, E-mail: absa@absa.org, Web Site: www.absa.org

**October 23-26, 2005**
American Biological Safety Association (ABSA) 48th Annual Conference
Westin Bayshore Hotel, Vancouver, British Columbia, Canada
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**October 15-18, 2006**
American Biological Safety Association (ABSA) 49th Annual Conference
Marriott Copley Hotel, Boston, Massachusetts
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ABS A Announces Professional Publications for Purchase

Anthology I: Perspectives on Laboratory Design—Contents include, in part: Management of Biosafety; Primary Biocontainment Devices; 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; 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.

Anthology II: Facility Design Considerations—Contents include, in part: 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; and Toxicology Laboratories.

Anthology III: 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; Biosafety Issues in Hospital Settings; An Overview: Biological Safety from a Global Perspective; Ergonomic Considerations in Biomedical Research Laboratories; and Applied Safety Training in the Biomedical Facility.

Anthology IV: Issues in Public Health—Contents include, in part: Autopsy Biosafety; Bioterrorism: Public Health Preparedness; Biological I Chemical Terrorism and the University; Global Perspectives on Infectious Substance Transportation; Biosafety Needs in Laboratories in Developing Countries; Understanding, Assessing, and Communicating Topics Related to Risk in Biomedical Research Facilities; Biological Safety and Public Health Laboratory Design; and Investigations of Emerging Zoonotic Diseases.

Anthology V: BSL-4 Laboratories—Contents include, in part: Emergence of Bacterial and Other Zoonoses: Why Always a Surprise?; Security Considerations for Microbiological and Biomedical Facilities; Working at Biocontainment Level 4—Contain the Operator or Contain the Bug?; A Class III Cabinet BSL-4 Laboratory; Medical Emergency Planning for BSL-4 Containment Facilities; Monitoring of Specific Contamination of Virology Laboratories During Work with Filoviruses; and Animal Necropsy in Maximum Containment.

Anthology of Biosafety VI: Arthropod Borne Diseases—Contents include, in part: Arthropod Vectors and Their Role in Transmitting Pathogens to Humans and Animals; Laboratory-acquired Infections; Biosafety Issues and Solutions for Working with Infected Mosquitoes; Working Safely with Recombinant Viruses and Vectors; Arthropod Containment Guidelines; and Biosafety Practices in Field Research: A Reviewed Experience.


Papers presented during the 4-day conference jointly sponsored by ABS A and CDC from February 6-9, 2000 in Atlanta, Georgia. This proceeding provides 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 shipping, transporting, and dealing with terrorism.

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**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.

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Other Requirements

1. Send five (5) typeset copies of each submission to: Editor, *Applied Biosafety: Journal of the American Biological Safety Association*, c/o ABSA, 1202 Allanson Road, Mundelein, IL 60060-3808, USA. 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, double-spacing, and full-justification. Indent paragraphs five (5) spaces. References, footnotes, table captions, and quotations should be single-spaced. Acceptable fonts are Times New Roman, Arial, AvantGarde, Helvetica, and Univers in 12 point. Avoid dot matrix printing. Primary headings should be flush left, bolded, and have the first letter of all main words capitalized throughout the submission. Secondary headings should be flush left, italicized, and have the first letter of all main words capitalized.

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