Chapter 1

Strategies for Coping with Multiple Biological Safety Regulations in High-Containment Laboratories

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Abstract

The increase in biological safety regulations and/or guidelines regarding personnel and facilities in high-containment laboratories demands constant vigilance by biological safety professionals responsible for safety in these environments. Safety professionals have been faced with legislative compliance issues in the past and have developed effective management methods to cope with the demands of these requirements. Examples include the impact of the National Institutes of Health (NIH) recombinant DNA (rDNA) Guidelines and the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard. This chapter describes seven successful strategies to manage regulatory compliance in research; these are based on an overall philosophy of developing a "culture of safety." Strategies range from interactive involvement with administration and research staff to biological safety professional development.

Introduction

Compliance with national guidelines for laboratories handling biological agents was a new concept in the 1970s. The Centers for Disease Control and Prevention (CDC) acknowledged the number of reported laboratory-acquired infections and first published a guidance document for ascending levels of laboratory containment based on the risk of the biological agent in 1974, *Classification of Etiologic Agents on the Basis of Hazard* (CDC, 1974). The National Cancer Institute (NCI) of the NIH also published tiered containment guidelines in 1974, *National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses*, based on the theoretical risk of laboratorians developing cancer from animal or human oncogenic viruses (NCI, 1974).

Scientists involved in the discovery and development of a new technology at the time, recombinant DNA, recognized the potential risk for biological hazards with the use of this technology. Led by Paul Berg, scientists convened the Asilomar Conference on Recombinant DNA on California's Monterey Peninsula in 1975 (Berg et al., 1975). Recommendations were made regarding safe-handling practices, physical containment, and biological containment that eventually became the basis of later biosafety recommendations. In 1976, the NIH published its first rDNA Guidelines that called for institutional and national review of rDNA experiments and elaborated on the biosafety principles

stemming from the Asilomar Conference (NIH, 2002). Of note, these scientists recognized the value of public scrutiny to avoid the perception of secrecy surrounding this new research tool that might foster illegal and immoral behavior. They also felt that, by involving the public in the Guidelines, scientists might avoid more restrictive legislation regarding how they conducted their work.

The NIH rDNA Guidelines have been the basis of safety practices since that time, and biological safety professionals have continued to adapt its principles when developing other major guidelines, such as the Centers for Disease Control and Prevention/NIH Guidelines for *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), first published in 1984 (Richardson & Barkley, 1984). Although advisory in nature, the CDC/NIH *BMBL* has become the community standard for biological safety compliance for over two decades.

The 1980s brought other safety concerns to the biomedical community with the identification of the human immunodeficiency virus (HIV). The CDC issued basic precautions when handling human blood or body fluids ("Universal Precautions"), followed in 1991 with regulations issued by the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard (CDC, 1988; U.S. Department of Labor, OSHA, 1991). Biological safety professionals were tasked with implementing basic safety practices and hepatitis B vaccine implementation with all human blood or body fluids, as opposed to only those identified with bloodborne pathogens. Following on the heels of the public fear of HIV and other bloodborne pathogens, the Environmental Protection Agency (EPA) issued Infectious Waste Guidelines in 1986, although never finalizing a federal regulation (U.S. EPA, 1986). Instead, state governments developed their own regulations on proper disposal practices. Biological safety professionals are now dealing with both federal regulations for safe practices for handling blood and body fluids in the occupational setting and individual state regulations for disposal of such waste.

Biological safety professionals also have had to confront legislation promulgated as a result of criminal acts, such as the Select Agents Rule (SAR). The SAR was initially enacted in 1996 to prevent transport of certain agents of concern because of the criminal activities of "bioterrorists" such as Larry Wayne Harris, who, in 1995, ordered *Yersinia pestis* through the mail (U.S. Congress, 1996). Later, after the anthrax letters were mailed anonymously in 2001, legislation was expanded to include such bioterrorism in the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") (U.S. Congress, 2001; U.S. Congress, 2002). The final Select Agent Rule with which biological safety professionals are familiar was legislated in 2003 under the Possession, Use, and Transfer of Select Agents and Toxins Interim Final Rule (42 CFR 73, 9 CFR 121, and 7 CFR 331), with the final rule effective in April, 2005 (U.S. Congress, 2003).

The impact of such legislation on their daily activities has been recognized by biological safety professionals for well over two decades. However, higher scrutiny and less tolerance of mistakes by the public have ignited a new round of proposed standards for laboratories conducting research with biological agents with high risk for transmission and/or morbidity. Since 2005, the U.S. government has created at least three groups to examine biosafety and biosecurity issues: the Working Group on Strengthening the Biosecurity of the United States, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and the National Science Advisory Board for Biosecurity (Executive Office of the President, 2009; DHHS, 2009; Gottron & Shea, 2009); for a thorough review of the legislative activities of these groups, see Linden, 2010). Legislation regarding the re-authorization and update of the Select Agent Program has been introduced into the U.S. House (HR 1225) and Senate (S 485), including requests for the National Academy of Sciences to review the Select Agent Program and recommend improvements (U.S. Congress, 2009).

The coping strategies developed by the biological safety community in the past to effectively manage compliance with previous guidelines and regulations can be useful in handling any emerging requirements.

Seven Strategies for Successful Compliance

Approach

The approach of any successful biological safety professional should be as an interactive partner with laboratory personnel, not as an enforcer of a multitude of requirements. The overarching philosophy should be that of developing a "culture of safety," meaning that safety is a shared responsibility among the institutional leadership and the workers, and is built upon an atmosphere of trust. Workers should feel empowered to ask questions and take ownership in the safety environment. The following suggested strategies for coping with current and emerging regulations/guidelines have a foundation in this philosophy.

Table 1
Seven Strategies to Cope with Multiple Regulations

1. Understand the Scope of the Institution
2. Administrative Support with Shared Accountability
3. Interact with the Institutional Gatekeepers/Leaders
4. Understand the Impact on the Workload for All
5. Develop Expedient Communication Strategies
6. Develop an External Network for Regulatory Awareness/Compliance Strategies
7. Seek Professional Development

Scope of the Institution

The first task for the biological safety professional is to determine the scope of the facility, the type of work, and his or her responsibilities in order to comply with relevant regulations/guidelines. The relevant regulations for a university basic science or biomedical research facility would be somewhat different than those for an industrial or manufacturing setting. Likewise, medical facilities with patient care responsibilities will have their own requirements. Veterinary and/or agricultural regulations would apply to institutions housing animals or operating greenhouses or field-studies for plants. The size of the institution would also determine the needs of the biological safety office. For example, do the responsibilities of the biological safety professional involve a single-site facility, or does the institution represent multiple sites in different states or even countries?

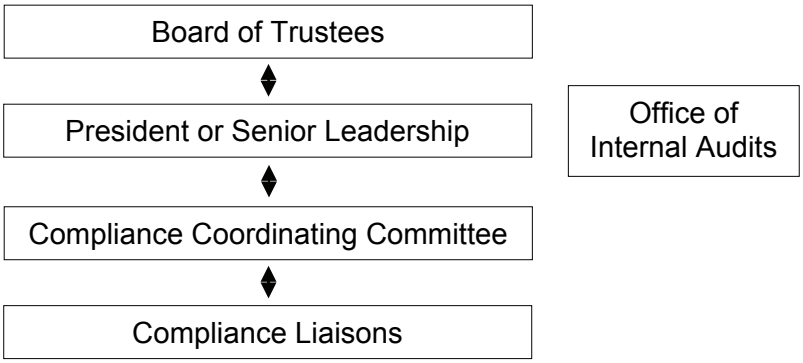
The biological safety professional also needs to determine if the facility requires additional security measures that involve biological materials. Compliance with the CDC/APHIS (Animal and Plant Health Inspection Service) Select Agent Rule impacts the biological safety office's interactions with either onsite security personnel or the local police department. The scope of the institution determines the type of training that can be conducted, the frequencies of onsite visits, the number of policies that need to be developed, the interaction with the community, and, importantly, the amount of administrative support required to effectively manage safety compliance.

Administrative Support

Administrative Accountability. The degree to which upper administration interacts with the biological safety office and shares in the "culture of safety" impacts overall institutional compliance. Institutions with such support generally have an administrative office to help shoulder the compliance responsibility, such as Offices of Compliance, Legislative Affairs, or Risk Management. Some of these offices may provide internal compliance monitoring, including audits for legislative compliance. Biological safety professionals should make contact with these services and even request an audit of the Safety Office.

Such administrative compliance offices may develop an internal process for such monitoring. An example is shown in Figure 1. In this process, as an example, compliance liaisons who are responsible for compliance with specific regulations and/or guidelines meet regularly with an institutional Compliance Coordinating Committee (CCC). The CCC assists in the development of an institutional vulnerability assessment to determine the strengths and weaknesses of the institutional-regulated community. Targeted areas for improvement are monitored by the compliance liaisons based on the degree of risk posed by non-compliance with the specific regulations. Regulatory risks could be classified as high, medium, or low for the probability of occurrence or impact on safety and health, financial issues, or reputation. The key to the success of this type of process is the commitment and involvement of upper administration to address problem issues and support remediation strategies.

Figure 1
Institutional Compliance Support Process (Example)



Administrative Support for Biological Safety. An interactive Institutional Biosafety Committee (IBC) is necessary to provide support and to review biological safety issues. Such a committee is required for institutions conducting recombinant DNA activities under the NIH rDNA Guidelines (NIH, 2002). Administrative for such committees is crucial to insure that they are informed about relevant issues and are given time and resources for meetings. Examples of appropriate administrative support would be funding members to attend conferences relevant to IBC activities.

New regulations and/or guidelines can involve additional needs for new or renovated facilities, supplies, training resources, and/or biological safety personnel. Biological safety professionals should partner with upper administration and serve as educators regarding not only the regulatory requirements, but also the additional support needed to comply with them. Safety professionals must have the ability to prioritize these needs.

Biological safety professionals should be able to approach the administration with requests for more personnel based on the prioritized needs. Unfortunately, no standard guidelines or recommendations indicate an adequate number of biological safety professionals to effectively manage the multitude of regulations. Some published surveys indicate how many FTEs (full-time employees) are currently devoted to biological safety in research settings. In 2008, Chamberlain (Chamberlain et al., 2009) surveyed biological safety professionals and found that 86% of institutions with both Biosafety Level 2 (BSL-2) and BSL-3 work employed at least one biological safety professional FTE compared with only 48% of institutions with only BSL-2 laboratories. In institutions with both BSL-2 and BSL-3 laboratories, 36% employed at least three biological safety professional FTEs.

More detailed information regarding safety positions and types of university research can be found in the frequent surveys conducted by the Campus Safety, Health, and Environmental Management Association (CSHEMA) (www.cshema.org). In Table 2, partial results of the Association's Benchmarking

Survey from 2008 are shown, categorized by research dollar expenditures. Clearly, those universities with more research expenditures have a higher number of FTEs devoted to biological safety than those with less research dollars (3.34 FTEs with highest vs. 0.9 FTEs with lowest expenditures). Of 76 university safety offices surveyed, the average number of biological safety FTEs was 1.57 (CSHEMA, 2010).

When the number of BSL-2 and BSL-3 laboratories associated with these universities is tabulated, the survey found that in universities that have BSL-2 but no BSL-3 laboratories, the average number of biological safety FTEs is 0.9, with 1.5 FTEs in universities with the highest research expenditures. In universities conducting research in both BSL-2 and BSL-3 settings, the average number of biological safety FTEs is 2.4, with 3.6 FTEs in universities with the highest research expenditures.

Of note is the workload on biological safety FTEs in universities with the highest research expenditures. The survey found that each FTE with responsibility for both BSL-2 and BSL-3 labs in highly funded facilities is responsible for an average of 113 labs. In contrast, their counterparts in highly funded universities with no responsibility for BSL-3 labs are responsible for 80 labs. Additionally, biological safety FTEs in the lowest-funded institutions are responsible for only 34 labs. As shown in Figure 2, highly funded research university institutions employ more biological safety FTEs; however, each of them is responsible for a higher number of labs, regardless of the presence of higher containment laboratories. The need for highly qualified biological safety professionals may be reflected in newer legislative requirements; however, these surveys also magnify the need for more positions, particularly when these FTEs are given responsibility for high-containment laboratories such as those handling Select Agents.

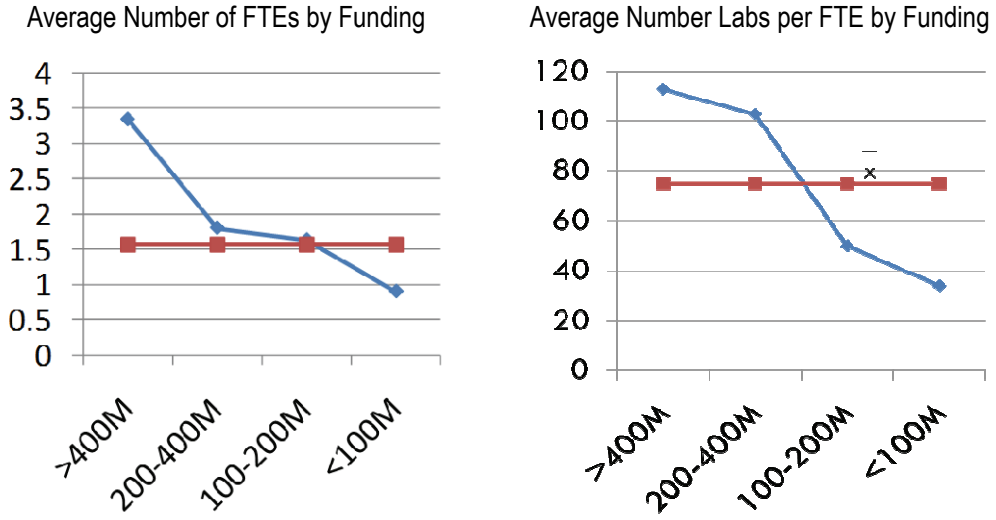
Table 2

University Biological Safety FTEs by amount of research expenditures.

University Annual Research Expenditures ($M)	# (%) with Both BSL-2 and BSL-3 Laboratories	Average # of Biosafety FTEs, BSL-2 AND BSL-3	# (%) with BSL-2, but NO BSL-3 Laboratories	Average # of Biosafety FTEs, but NO BSL-3	# (%) Associated With Medical Schools	Avg. # FTEs Devoted to Biological Safety
400-865	11/13 (85%)	3.6	2/13 (15%)	1.5	12/13 (92%)	3.34
200-400	9/13 (69%)	2.4	2/13 (15%)	0.5	9/13 (69%)	1.8
100-200	12/15 (80%)	1.8	3/15 (20%)	0.86	6/15 (40%)	1.63
<100	12/35 (34%)	1.9	15/35 (43%)	0.74	9/35 (26%)	0.9
Total	44/76 (58%)	2.4	22/76 (30%)	0.9	36/76 (47%)	1.57

Adapted from the CSHEMA (CSHEMA, 2010). Benchmarking Survey of 76 University Health and Safety Offices, 2008.

Figure 2
Biological Safety FTEs by Research Funding



Adapted from the 2008 CSHEMA Benchmarking Survey of 76 University Health and Safety Offices, (CSHEMA, 2010).

Interact with Institutional Gatekeepers and Leaders

Effective biological safety management cannot be accomplished in isolation. Interaction with other institutional departments is necessary to insure compliance and to be certain necessary policies are conducted. Examples of institutional departments that all biological safety professionals should be contacting for this collaboration include:

- Employee Health
- Animal Research Services
- Facilities Management
- Equipment Procurement
- Grants/Contracts
- Risk Management/Office of Compliance
- Committees: Institutional Animal Care and Use Committee, Institutional Biosafety Committee, and Institutional Review Board
- Greenhouse Managers
- Campus Security/Police
- Computer (IT) Services

Interactions with most of these services have been the historical foundation for effective biological safety management in coping with past regulations or guidelines. More recently, with the implementation of the Select Agents and Toxins Rule (U.S. Congress, 2009), security personnel have begun to play a more important role in biosecurity compliance. Computer services have become

important to develop databases, web sites, and, in many cases, online training and tracking for compliance.

Understand the Impact of New Requirements on the Workload of All

Importance of Approach. Researchers are busy and need to comply with many requirements in addition to safety. Paperwork demands are growing and research funds are competitive. To achieve the “culture of safety” in an institution, biological safety professionals must be able to coach rather than enforce. Researchers must be able to trust that the safety office will not impart unnecessary restrictions but is part of a team effort for a continuous safety environment. The focus of safety should be on a thorough risk assessment of the laboratory work, followed by assistance in compliance with any relevant requirements. Most researchers will comply with safety requirements and even recommendations when given scientific justifications for the rules.

Examples of Coaching. The more time researchers spend on evaluating their safety needs and developing safe practices and the less time they spend on meaningless paperwork or formatting issues, the more likely will be their compliance. The effective biological safety manager can provide assistance in several ways.

Biological safety professionals can develop templates for a variety of required documents, such as Standard Operating Procedures, safety plans, and biohazard signage. The important adjunct to this, of course, is assistance with completing the forms. Likewise, checklists can be made available to researchers for use with laboratory self-audits, lists of required documents to send for IBC protocol submissions, etc. Templates, checklists, manuals, and links to associated guidelines and regulations should be located on a customer-friendly web site.

Training should be applicable and relevant to the research laboratory. Biological safety professionals should be creative in providing required safety training for any activity that demonstrates that the researcher truly understands laboratory safety. For example, participation in a thorough laboratory audit by the biological safety office where the researcher demonstrates appropriate documentations, practices, and laboratory containment can serve as an annual laboratory safety-training credit.

Develop Expedient Communication Strategies

In the past, safety offices have typically distributed posters or newsletters to communicate safety updates. These continue to be useful tools, but in the age of mass communications, expedient notifications have become easier. Some useful strategies may include development of a quick e-list of laboratory safety contacts. E-lists may prove useful when compliance issues begin to emerge in several labs. A quick e-mail to lab contacts may resolve the issue in a timely manner.

The safety web site should contain all useful links, such as those discussed above, be easy to use, and be up-to-date with working links. Safety contact names, e-mails, and phone or page numbers should be readily available on the site. A link to a general safety site (i.e., “Contact Us”) for questions to be sent and answered in a timely manner is also helpful. Another useful link connects to a customer service survey, where employees can evaluate interactions with safety personnel and describe problems or provide kudos to those individuals. An example of a customer service survey tool from Duke University is shown in Figure 3. Feedback from such online survey tools can be timely in providing

Figure 3
Example of Customer Service Survey Tool

Duke University Occupational and Environmental Safety Office
Customer Service Survey

This survey is designed to measure and improve our customer service efforts. If you have an immediate safety issue, please send us an e-mail: safety@duke.edu.

Who was the primary service provider? _____

What was the nature of your contact with OESO _____

Statement	Check as Appropriate
Staff was courteous	Strongly Agree Agree Disagree Strongly Disagree N/A
Staff was helpful	Strongly Agree Agree Disagree Strongly Disagree N/A
Staff provided complete and accurate information	Strongly Agree Agree Disagree Strongly Disagree N/A
Response was timely	Strongly Agree Agree Disagree Strongly Disagree N/A
My overall experience was positive	Strongly Agree Agree Disagree Strongly Disagree N/A
Overall, my expectations were met	Strongly Agree Agree Disagree Strongly Disagree N/A

If you feel that we fell short in meeting your expectations, please describe the situation and the date of the incident:

As a result of your experience, what improvements can you recommend?

useful suggestions to the safety office and may provide employees with a sense of control over their safety culture.

Finally, biological safety professionals should make sure that researchers know how to access the safety web site. A question on a laboratory audit tool can prompt the safety representative to help lab personnel bring up the web site and navigate through the most important links.

Develop an External Network to Assist with Regulatory Awareness and Compliance

Networking. Since keeping up with regulatory updates is almost a full-time job, biological safety professionals benefit from their professional organizations, such as the American Biological Safety Association (ABSA) or the American Society for Microbiology (ASM). Such organizations typically provide professional conferences, seminars, journals, books, newsletters, and web sites with updated information. National conferences provide not only insight into the latest relevant proposed regulation or recommendations, but also the opportunity to meet other professionals in the field and to hear about strategies developed by successful programs. Even attendance at meetings of local chapters or affiliates of the larger organizations can enhance these networking opportunities. Many e-mail professional list serves are available that allow interaction with other professionals on a daily basis and provide a forum for safety questions about specific issues (e.g., the biosafety discussion list, e-mail: listserv@listserv.nethelps.com with sub biosafety in the body of the e-mail, or the ABSA occupational health discussion list: listserv@biosafety.absa.org with the message subscribe ABSA_OCCHEALTH).

Web Sites. Professional organizations also provide useful web sites with links to specific regulations and/or guidelines. For example, ABSA's web site (www.absa.org) contains a link to current biological safety regulations/ guidelines, agencies, and agency alerts under the "Resources" tab, "Biological Safety Links." For proposed legislation, the web site provides a tab for "ABSA in action" where there are several helpful links. For example, "Legislative Issues" provides links to proposed legislation regarding biological safety-related issues, as well as to information on ABSA professional responses to these regulations; "High Containment Lab Accreditation Task Force" describes ABSA's initiation of standards for accreditation of these labs.

Involvement in the Law-making Process. Providing input into proposed legislation is an excellent way for biological safety professionals to help determine the outcome of the legislative language and their ability to comply. On the national level, Senators and/or Congressmen can be contacted directly through their offices. Other governmental agencies or committees, such as the Executive Order Working Group on Biosecurity, the National Academy of Sciences, or the National Science Advisory Board on Biosecurity, can also be contacted. Academic institutions may have an Office of Public Affairs or a

Communications Department that assists in the promotion of professional insights or opinions about bodies of legislation.

These and other suggestions are discussed in an open letter from the ABSA Legislative Committee on the ABSA web site. This committee provides an update on the impact of emerging legislative requirements for the biological safety community.

Seek Professional Development

The qualifications for biological safety professionals and others associated with high-containment laboratories have been discussed in several recent reports and proposed legislation. In the *Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight* (DHHS, 2009), recommendations included the credentialing (certification or registration) of biological safety professionals with oversight of biosafety and biocontainment programs at all high- and maximum-containment research facilities. The Congressional Research Services Report, *Oversight of High-Containment Biological Laboratories: Issues for Congress* (Gottron & Shea, 2009), describes the need for standardized training for personnel working in high-containment labs. The same issue is under consideration in the Select Agent Re-Authorization legislations (U.S. Congress, 2009).

Regardless of the future mandate for credentialed or highly trained biological safety professionals, professional development is a cornerstone strategy for coping with multiple regulations. Many opportunities are currently available to continue one's education in the biological safety field. The Trans-Federal Task Force Report describes many of these in Appendix H (DHHS, 2009). In addition, conferences, seminars, webinars, articles, and other valuable sources of information for training and professional development are available on the ABSA web site. ABSA currently offers the certification of biological safety professionals (CBSP) through a combination of educational courses, work experience, and exam. The NIH provides a 2-year fellowship program for novice biological safety professionals to participate in intensive safety training on the NIH campus [the National Biosafety and Biocontainment Training Program (NBBTP)]. The goal of the program is to train certified safety professionals who are capable of managing the safety programs at high-containment research facilities (www.nbbtp.org). Additionally, the NBBTP program provides professional development courses for biological safety professionals currently working in the field who need updated courses.

Conclusion

Strategies for coping with multiple regulations and/or guidelines have been developed by biological safety professionals for several decades, based on the approach of developing a "culture of safety." In anticipation of further regulatory oversight of high-containment facilities, this chapter discusses seven strategies that have proven to be valuable in her institution for over two decades.

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