
Preface

The central premise of this book is that the biological research, clinical, diagnostic, and production/manufacturing communities need to embrace and implement biorisk management systems in their facilities and operations. In most countries, the current system mitigates the risk of accidental infection, accidental release, and intentional misuse of pathogens and toxins based on general, predetermined biosafety levels and/or prescriptive biosecurity regulations. Although this approach may have sufficed when the biological life science community was relatively small, and work with particularly dangerous organisms was limited to a few countries and facilities, the life sciences have grown significantly in the last two decades—in both scope and sophistication. Much of this growth has extended well beyond North America and Western Europe, and deep into the developing world. Simply, there are more people in more places working with, and even creating, more dangerous pathogens and toxins than ever before—and that trend shows no sign of abating in the future.

Increased risk inevitably comes with this expansion. The past 20 years have been marked by multiple safety and security incidents at bioscience facilities around the world, including many notable incidents at so-called sophisticated facilities in North America and Western Europe. Clearly, the current system that is based on biosafety levels and security regulations does not work effectively enough. It is time for the bioscience community to learn some lessons from other high-consequence industries that have experienced devastating accidents, and that have intellectually evolved their own approaches to safety and security well beyond generic, predetermined, technical checklists. These industries have almost universally adopted what is now referred to as risk management systems. This book urges the global bioscience community to embrace biorisk management—before a devastating accident threatens to jeopardize the entire bioscience enterprise.

This book is organized into 11 separate chapters, and each chapter focuses on a different element of a biorisk management system. Different experts from around the world have written each chapter, demonstrating that the biorisk management system espoused by this book is globally applicable. The first chapter defines biorisk management, details the history of the field of biosafety and biosecurity, and makes a case for implementing biorisk management to prevent a major incident by drawing comparisons to disasters in other industries. The second chapter describes the AMP model, which is a framework that uses the components of assessment, mitigation, and performance to structure and implement a comprehensive biorisk management system. Chapter 3 defines the risk assessment process, and explains how to assess and prioritize various risks, and ensure that a risk assessment fits into a biorisk management system. The fourth chapter illustrates how to use the risk assessments to inform a design strategy to avoid overengineering a facility and wasting valuable resources.

The fifth chapter evaluates the roles of the different mitigation measures, including laboratory practices and procedures, safety and security equipment, and personnel management. The specific combination of mitigation measures should be determined based on the risk assessment, and evaluated according to specific

performance metrics. Chapter 6 argues that a flexible and adaptable training plan is more effective than a rigid standardized compliance plan, since it can be strategically implemented to manage risk in a number of different settings and contexts with the ability to meet the challenge of new hazards or threats.

Chapter 7 argues that reliability-centered maintenance should be the framework for a biorisk management maintenance program. The eighth chapter advocates for utilizing specific performance indicators, instead of relying on failure data, for proactive activities and outcomes to make effective changes and improvements to a biorisk management system. The ninth chapter suggests that a comprehensive biorisk management system must include a risk communication plan designed to address both normal operations and emergency situations from an internal and an external perspective.

Chapter 10 is a case study that examines the biosafety incidents that took place at the US Centers for Disease Control and Prevention and the US National Institutes of Health in 2014. Finally, Chapter 11 identifies some of the most important challenges that face the biorisk management community by examining current gaps and shortcomings in contemporary biorisk management understanding and approaches. It also presents a series of opportunities to enhance the practice of biorisk management in the future.