

# 'Laboratory Biorisk Management' details safety, security methods for biosciences sites

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Two Sandia National Laboratories senior managers, Jennifer Gaudioso, left, of the International Biological and Chemical Threat Reduction Program and Ren Salerno of the Biological Sciences and Technologies Program put years of experience improving safety and security at biosciences facilities worldwide into “Laboratory Biorisk Management.” The new book, containing chapters co-authored by other Sandia researchers and international experts, is the first full-length manuscript on the detailed implementation of biorisk management. Credit: Randy Montoya

Recent mishaps at laboratories that mishandled potentially dangerous biological substances and the transmission of the Ebola virus in a U.S. hospital are symptoms at bioscience facilities that two Sandia National Laboratories researchers think could be prevented by implementing the practices in a new book on biorisk management.

The 228-page "Laboratory Biorisk Management" published by CRC Press was edited by two Sandia senior managers, Ren Salerno of the Biological Sciences and Technologies Program and Jennifer Gaudioso of the International Biological and Chemical Threat Reduction Program, who have worked for years to improve safety and security at bioscience facilities worldwide.

"This is the first full-length manuscript on the detailed implementation of biorisk [management](#)," Salerno said. "Laboratory biorisk management is fundamentally a culture of rigorously assessing risks, deciding how to mitigate those risks deemed to be unacceptable and establishing mechanisms to constantly evaluate the effectiveness of the control measures."

Salerno, Gaudioso and the other authors advocate a cultural shift in how laboratories, hospitals and other bioscience facilities approach safety and security. They say, biorisk management should:

- prioritize an intellectually sound, evidence-based decision-making process using substantive risk assessments to evaluate a facility's risk based on the unique operating environment.
- require implementation of mitigation measures according to the risks of specific activities, experiments or projects.
- constantly assess performance.
- emphasize more meaningful roles and responsibilities for all

personnel within a facility.

- assign ultimate responsibility for safety or security performance to top management.
- be scalable from the smallest hospital or clinical lab to the largest research institution.

About a dozen other Sandia experts in the field paired up with their international counterparts to develop and advance a practical set of concepts relevant and able to be implemented by labs worldwide, Gaudioso said.

In addition to explaining biorisk management and providing a model, the book includes chapters on risk assessments, facility design and controls, training, operations and maintenance, how to evaluate biorisk management performance, communications issues, case studies and future directions and challenges for biorisk management.

## **Book authors say growth of biosciences necessitates need for change**

The time to rethink the safety and security of biosciences facilities is now because of the expansion in scope, scale and sophistication of the biosciences field over the last 15 years, Salerno said. Examples of this expansion include the rapid advance of synthetic biology and, following the 2001 anthrax attacks on the White House and Congress, the deep integration of biosciences within national security research.

"The times are changing and what we have never done in the biosafety community is take a good hard look at why we do what we do and ask ourselves if the system needs to be radically reshaped in light of all the changes in biology," he said. "From our perspective, this is way overdue."

Today's biosafety guidelines were created in the early 1980s. The Centers for Disease Control and Prevention partners with the National Institutes of Health to publish biosafety guidelines to protect workers and prevent exposures in biological laboratories, Salerno said.

The current guidelines tier biological agents into four risk groups and designate work with those agents into one of four biosafety levels. Salerno says use of the guidelines has become perfunctory and their nuances are not widely understood by many personnel at bioscience facilities. For example, he said, it has become common practice in the field is to share risk assessments or material safety data sheets between facilities, so that they no longer take into account the unique circumstances of each facility, including location, the type of work done there and the expertise and training of its personnel.

"I believe the events of the last year in this field demonstrate exactly what we've argued: that the current system is broken. It's a systemic problem," Salerno said. "We've created an administrative-based safety culture in biology that is way too simplistic for the level of complexity of today's science."

## **Global assistance in laboratory security brings issues to light**

Sandia scientists became more aware of the issues through their work over the past 15 years with laboratories around the globe.

In 2008, the European Committee for Standardization hosted an international workshop that published an agreement among 24 countries, introducing an overview of biorisk management. The World Health Organization (WHO), which quickly adopted the biorisk management framework, asked Sandia and other technical advisers to create a two-

week Biorisk Management Advanced Trainer Programme, which Sandia experts helped teach in 2010-2011.

"We were barely scratching the surface and everybody wanted more information, more detail and wanted to understand how to implement the concept," Salerno said. "That's when we began talking about the need for a manuscript."

In addition to the book, Sandia also curates the Global Biorisk Management Curriculum, which contains 47 separate courses developed by Sandia and others and is being taught by 500 trainers worldwide, Gaudioso said.

## **Book says focus on performance can prevent problems before they happen**

Salerno said the book promotes the idea that a good biorisk management system determines ahead of time the metrics that will show a project, experiment or activity is being done safely and securely.

The [risk assessment](#) completed before an activity has begun sets leading safety and security performance indicators. Then, regular monitoring and documentation will show whether the activity is achieving the safety and security goals, enabling scientists to identify things that are working fairly well, but perhaps not perfectly, while the activity is in progress, he said.

"In other words, by evaluating performance you can adjust your safety measures before something happens," Salerno said. "You don't want a bad thing to happen to determine whether or not your system is working."

Some might view this as added paperwork, but Salerno and Gaudio point out that experience in other high-consequence industries shows that when processes are more effective and efficient, a more effective safety system is the result, which in turn leads to decreased costs and improved productivity.

Gaudio explains that a lot of the risk assessment and mitigation work in the book should help institutions solidify good practices and fill in gaps in their procedures.

"The burden should be proportionate to the risk, so that you're not asking too much from people who are carrying out activities that don't present a lot of risk to themselves or the community," she said. "But for people whose activities carry more significant risk, then yes, they have to do a little bit more to make sure they are managing those risks appropriately. I don't think that's an unreasonable thing to ask."

## **Culture change in biosciences required for biorisk management**

Salerno recognizes that the system outlined in the book won't work unless stakeholders in the biosciences community buy into the concepts.

"If someone takes this book, agrees that the performance chapter makes some good points, but then adds a large number of additional and perhaps arbitrary requirements, the system will look like yet another administrative checklist. That would be counterproductive," he said.

In the final chapter, Sandia researcher Ben Brodsky and a co-author write that biorisk management is a relatively young approach that faces challenges to being implemented broadly.

More evidence is needed to show whether biorisk management works, so they call on more organizations to develop ways to measure the performance of biorisk management and to show how it benefits an organization.

"This will enable the biorisk management community to continue creating tangible benefits for the bioscience community, including keeping society and the environment safe while more efficiently facilitating the delivery of science," they wrote.

Provided by Sandia National Laboratories

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