Maximizing Safety and Uptime at Kansas State University's Biosecurity Research Institute

Operating Assurance Model Standardizes and Centralizes Facilities Activities

The need to minimize risk governs almost every aspect of building operation at biocontainment facilities, presenting special management and operational challenges. With safety and security such paramount priorities, the rigorous environment is further complicated by sophisticated infrastructure, multiple user groups, and a mix of personnel with varied competencies and skill levels.

“Biocontainment operations management is complex,” says Scott Rusk, director of Pat Roberts Hall, the home of Kansas State University’s Biosecurity Research Institute (BRI). “We have to coordinate protocols and activities for day-to-day repairs under predictive, preventive, and responsive maintenance models. Facility systems performance must be tested and verified at least annually.”

These functions must be achieved in tandem with meeting compliance requirements for biosafety, biosecurity, and biocontainment, each of which protects a different target: people, materials environment, and the facility, respectively.

“The effort to manage all these components requires an extensive continuous communication process among all levels at the facility, from animal care and custodial staff all the way to the research director and the principal investigators,” says Rusk.

Clean Slate, No Silos, Baby Steps

The BRI’s role is to provide a safe, secure, and functional environment to support and promote the scientific mission. From the earliest facility planning, three favorable forces helped accomplish this objective: clean-slate management, an absence of silos, and a “baby-step” approach.

The new facility afforded the opportunity to implement policies and procedures from scratch, on a clean slate. The fresh start, combined with Rusk’s extensive experience in biocontainment operations, allowed the facilities team to determine and incorporate best practices even before any research began.

“Our operational guidelines are not so different from what may exist in similar organizations, but being able to formulate and establish them well before the facility opened was a definite advantage,” he notes.

The no-silos approach unites all occupants in understanding and appreciating the vital functions that take place both in and outside the labs.

“The researchers need to understand what must be done to keep the boilers operational. Conversely, operations support staff need to have a very good understanding of why the research that is happening in the building is important. We include everyone as much as possible,” says Rusk.

A slow but steady pace—“baby steps”—has helped ensure that one level of regulatory complexity, blended with the logistics of supporting research, is mastered before advancing to the next.

“We could not start with high-hazard or high-risk activity right out of the box,” says Rusk. “Each research project is unique in its own right and requires us to evaluate how to manage it.”

A facilities operating assurance model provides the framework to integrate all essential

information—critical risk points, policies and procedures, infrastructure descriptions, equipment instructions, research schedules, communications flow—to make certain the building functions as necessary.

BRI Details

Construction of the 113,000-sf Biosecurity Research Institute began in 2004. It is designed to house enhanced BSL-3 laboratories, insectary, and vivarium; BSL-3Ag domestic livestock holding; an enhanced BSL-3 food safety and food security area, which can accommodate full-scale "farm-to-fork" food processing; and an interactive training and education suite for researchers and operations support staff, as well as visitors, collaborators, and outside organizations.

Support infrastructure includes an on-site high-pressure boiler system, an on-site waste treatment system with three 4,000-gallon liquid effluent treatment tanks and a 5,000-pound alkaline hydrolysis digester, redundant electrical power and a standby generator, on-site chillers and zone-redundant HVAC systems, and a full interstitial mechanical floor.

After four years of construction, commissioning, and performance verification, the facility opened in 2008 to very low-hazard research with no regulatory permit requirements. Regulated work with a few pathogens began in 2009 and continues to escalate. The progression has been measured and methodical, deliberately intended to advance gradually, with the flexibility to redirect processes and procedures as the need arises.

"BRI is a new venture in higher containment for the university," Rusk says. "A gradual upward movement into what we were ready to manage has allowed us to test and evaluate the operating protocols we developed and modify them with very low risk."

BRI is nearing full occupancy. Approximately 100 people are authorized and trained to work in the facility, from scientists and technicians to IT staff and maintenance personnel. Rusk estimates there is room for roughly 40 more. From an operations perspective, BRI has the ability to host the highest levels of BSL-3 research.

Referencing the crawl-walk-run-fly spectrum, Rusk notes, "We're in between the running and flying stages."

The Operating Assurance Model

The facility operating assurance model is the integrated, multifaceted plan to ensure the three key goals of the BRI are met: preventing hazardous exposure, minimizing interruptions to the scientific program, and meeting building system efficiency targets. The model centralizes and standardizes all facility-related activities in a formal program. It is integrated throughout the Institute by a network of forced communications, including signatory authorities, and clearly defined performance standards for building systems. The backbone of the operating protocol manual was developed with the assistance of Merrick & Co. consultants Chris Kiley, Gilles Tremblay, and Art Wyatt.

Before any specific guidelines could be finalized, the facilities team conducted a risk assessment to uncover the principal operating hazards or vulnerabilities so the most critical scenarios could be addressed.

"We needed to identify the overall and day-to-day things that could put people, an experiment, or containment at risk," Rusk explains. "That way, if a mechanical problem crops up or unscheduled maintenance is required, we have a very structured path to resolution that ensures safety will not be

compromised."

The team also identified existing resources to support the integrated program, for example, baseline performance data, the centralized maintenance management system, design and engineering records, preventive maintenance plans and manuals, and training programs.

The result is the operational protocol manual, an exhaustive collection of information on all things building-related. The content includes both general and specific facility descriptions, descriptions of key biocontainment systems, and an outline of roles and responsibilities (management, line supervision and workers organization chart). The manual then drills down into policies, procedures, task instructions, maintenance records, location of reference documents, equipment manuals, and approval and permits.

The manual's task instruction forms constitute the primary vehicle for communicating all relevant information for maintenance procedures. Biocontainment work must be permitted through the facility organization, and appropriate approvals must be obtained and documented.

The actual instructions detail specifics such as how to shut down a system; whether decontamination is required, and, if so, what techniques to use; and whether the procedure is preventive maintenance or part of a demand maintenance schedule.

The instructions also spell out the degree of risk associated with an individual system, indicating whether it has a low, medium, or high impact on both scientific research and overall building function. This connection is particularly important for the operations staff, who are usually neither biosafety nor biocontainment specialists, Rusk points out. It is essential to the overall facility mission for them to understand the role of the equipment they are working on.

For example, a routinely scheduled air handler shutdown is considered to have medium impact thanks to a scheme of redundant units. On the other hand, the shutdown for HEPA filtration certification and change-out is high impact because typically only one HEPA housing services the space directly below it. Because there is no redundancy, additional coordination and risk assessment are necessary.

"Maintenance personnel without this key information might close off the HEPA housing while scientists were doing research in the lab below," Rusk notes. "We have to coordinate maintenance tasks with the research teams, too."

Task instructions also include granular detail about the procedure itself, such as which switch to throw and where it is located, complete with diagrams and images. A sign-off component on the back page confirms approval on task completion.

While Rusk does not have any specific cost data on the operating assurance model, he does say it was deployed at little additional cost, especially in view of the high return on investment in scientific productivity and occupant morale.

Overcoming Obstacles

Rusk emphasizes that training and communication are an integral part of the wide-ranging effort. Many of the potential roadblocks to implementation spring from cultural and organizational differences, and staying on task can be a challenge.

"We're all busy, and everyone has other roles and responsibilities," he observes. "It is easy to get distracted."

The best way to overcome these obstacles is by creating a universal sense of ownership and pride in the BRI.

“We follow the operational model because it greatly enhances our ability to minimize risks, improves coordination and efficiency of research capabilities, and it is the right thing to do,” he says. “It’s critical to have everyone on board and aware of the benefits. People sometimes assume someone else has the ball. The model gives us the opportunity to find out who has the ball at every step of the way. It is how we confirm that we are providing safe and successful biocontainment operations.”

By Nicole Zaro Stahl

Biosecurity Research Institute

Photo by David Mayes, Kansas State University Communications and Marketing

After four years of construction, KSU's 113,000-sf Biosecurity Research Institute opened in 2008 to very low-hazard research with no regulatory permit requirements. The new facility presented the opportunity to implement policies and procedures from scratch, on a clean slate.

Mechanical Systems

Photo by David Mayes, Kansas State University Communications and Marketing

The BRI's operating assurance model provides a very structured path to resolve any mechanical problems so that safety will not be compromised.

Plant Research

Photo by David Mayes, Kansas State University Communications and Marketing

The gradual introduction of regulated work has allowed BRI management to test, evaluate, and modify operating protocols with very low risk.

Biography

As director of Pat Roberts Hall, home of the Biosecurity Research Institute at Kansas State University, Scott Rusk is in charge of administrative and technical management of BSL-3 and BSL-Ag biocontainment facilities. He works with the Institute's research director, biosafety officer, and facility operations groups in the planning, development, and execution of research, training, and education programs. Rusk holds a master's degree in Veterinary Microbiology and Preventative Medicine from Iowa State University and has over 28 years of experience in biocontainment laboratory operations and management. He was previously assistant director of USDA's National Animal Disease Center and a biocontainment operations specialist with Flad Architects.

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