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## Reports find UW lab oversight weak

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UW-Madison image

UW-Madison professor Gary Splitter, a tenured professor in the School of Veterinary Medicine, won't be a

UW-Madison professor Gary Splitter conducted his infectious disease research in one of the university's highest security labs. To work with brucella, a restricted germ, he and his staff had to pass FBI background checks and fill out piles of paperwork.

Despite the precautions, at least two of his staff got infected with brucellosis — one with cysts in the brain. And in a separate incident, members of Splitter's lab broke federal rules by creating an unauthorized, drug-resistant strain of the disease.

The problems in Splitter's lab highlight potential risks of dealing with biological materials. An investigation into the unauthorized experiments cost him dearly — he lost his lab privileges for five years — but it also revealed serious deficiencies in the university's biosafety system.

Two reports show UW-Madison allowed its Office of Biological Safety to crumble in recent years, at the same time that research on campus was growing dramatically.

Within the last year, UW-Madison strengthened its oversight of research, more than tripling the size of the biosafety office and revamping its training for researchers.

But Splitter charges that if the university had the appropriate education and safeguards in place a few years ago, the incident in his lab never would have happened.

“It was a meltdown waiting to happen,” Splitter said.

### **Keeping up with growth**

UW-Madison officials say the infrastructure is now in place to safeguard the public.

But safety systems did not keep up with tremendous growth over the past 10 years, when research expenditures went from around \$550 million to nearly \$900 million.

UW-Madison is one of the largest research universities in the world with more than 500 scientists — known as principal investigators — conducting studies involving biological material on campus. Of those, six work with the riskiest materials, those known as select agents or toxins.

These are germs, like brucella, which the U.S. government has determined could pose a severe threat to public health and safety.

Those who work with such materials must pass an FBI background check and go through specific training. Their proposed studies must also be approved by a campus committee, made up of faculty, staff and the public, and they undergo annual inspections by staff from the university's Office of Biological Safety.

However, that office got down to a low of just three members about a year ago. And UW-Madison has more than 2 million square feet of lab space to cover.

## **Lack of training**

A May 2009 report from the investigation into Splitter's lab, by emeritus engineering professor Stephen Robinson, found that "of the senior people I talked with, not one said the campus biosafety system was working well, or even acceptably."

The investigation found that between 2004 and 2007, two graduate students and a post-doctoral employee had created antibiotic-resistant strains of brucella. This is known as a Major Action and requires federal approval, which Splitter did not get.

Robinson reported that one of the reasons why Splitter failed to effectively supervise his laboratory and personnel was because the campus did not train him well enough on the federal rules regulating antibiotic-resistant germs.

“I believe a large share of that blame should instead accrue to the campus because of the serious deficiencies in its biosafety system,” he wrote.

In fact, the federal government fined the university \$40,000 for the experiments.

However, Robinson also faults Splitter for not informing the proper committee about the experiments going on in his lab. The university shut down Splitter’s lab in December 2008, but reopened it in the spring of last year under the supervision of scientist Jeremy Harms.

The two graduate students involved were not disciplined. The post-doc resigned after learning of the investigation, said Bill Mellon, associate dean for research policy.

“It’s clear that the P.I. (principal investigator) is responsible and needs to know the regulations,” Mellon said. “You agree when you do this work what you can and can’t do.”

### **Safety office understaffed**

After officials learned of the incident in Splitter’s lab, they commissioned an external report by Claudia Mickelson, deputy director of the Massachusetts Institute of Technology’s environment, health and safety office.

She found that the Office of Biological Safety was understaffed. Although two positions were vacant at the time, she indicated that even if staffing returned to its former level, “it is still too low.” She also recommended that the biosafety office staff needed to better communicate with researchers.

“An incident as complex as the one (involving Splitter) always indicates a process failure,” she wrote.

Last July, UW-Madison hired a new biological safety officer, Jim Turk, who subsequently added five new inspectors and two people to train researchers on rules and regulations. His staff also includes an assistant officer and a compliance expert.

The university now requires that researchers go through three training modules: basic biosafety, National Institutes of Health guidelines and safety with needles/syringes.

Turk said even when the office got to its lowest staffing, it continued to inspect labs using high risk materials annually. But it wasn't hitting the lower security labs “as frequently as is ideal,” he said. He said he's also trying to create an atmosphere of cooperation with researchers rather than one of fear.

### **Infected lab workers**

It is relatively rare for lab workers to get infected from the agents they study.

The university reported about six potential exposures, which include needle sticks or animal bites, to the National Institutes of Health within the last year, Turk said. None of those incidents involved anyone becoming ill, he said.

The two individuals who got sick in Splitter's lab are not connected to the university's investigation into Splitter.

A graduate student got brucella cysts in her brain before the drug-resistant strains were created in 2004. She took some time off school but fully recovered and returned to the UW-Madison doctorate program, Splitter said. The other case was

not as serious and that person also recovered, he said. Brucellosis is primarily passed among animals, but can spread to humans and cause symptoms such as fever, joint pain, fatigue, and in severe cases, infections to the nervous system.

Splitter said because the disease is highly infectious, he doesn't know how the workers got sick.

One of the world's leading researchers in brucellosis, Splitter has brought in more than \$16 million in grants to UW-Madison and published more than 160 papers.

He is complimentary of the changes the university has made to help researchers understand the maze of rules required by federal and local authorities.

“We want to follow the rules as best we can, as closely as we can, to make sure we're in compliance,” he said.

But Splitter said he also decided to take safety measures on his own. Now staff wear protective gear, “essentially space suits,” in the lab, he said.

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