**Ask the Experts**

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Do you have a biosafety question and you’re not sure who to ask? Send your questions to the “Ask the Experts” column and I’ll get them answered for you. Drawing from my own experience or that of other experts in the field, we’ll try to compile a thorough and comprehensive answer to your question. Please e-mail your questions to jkeene@biohaztec.com or Co-Editor Barbara Johnson at barbara_johnson@verizon.net or Co-Editor Karen B. Byers at karen_byers@dfci.harvard.edu.

*“Responsibility Without Authority is Futile”*

According to Emily Ramshaw of the Dallas Morning News in her article entitled “CDC Reprimands Texas A&M Over Lab Safety” on September 4, 2007:

“...Among the shortfalls identified in the university’s bio-defense program:
- At least seven cases where Texas A&M allowed unauthorized access to select agents, including Brucella and Q fever.
- Several vials of Brucella, an infectious bacteria, were reported missing or unaccounted for.
- Poor record-keeping in logbooks of individuals entering and leaving campus labs.
- Lab workers failing to wear protective respiratory equipment and wearing coats used for experiments out of the lab setting.

The university “did not sufficiently address the particular needs of the individual, the kind of work they do, and all of the risks posed by the select agents,” the report notes.

Since June, when news reports of the infection and exposures surfaced, the university has acknowledged failing to properly notify the Centers for Disease Control and Prevention (CDC) of the cases, which involved dangerous agents that could be used as bioterrorist weapons.

University officials have also admitted two other mistakes: conducting experiments in labs not approved for them, and allowing unauthorized lab workers to use the agents. ...”

Please notice the emphasis on: “...Texas A&M; ...The University...; ...University officials...,” not on the Office of Environmental Health and Safety personnel. Yet the safety professional feels the pressure of ensuring compliance with the requirements.

As health and safety professionals struggle with personnel, principal investigators, and middle managers regarding compliance with select agents, bloodborne pathogens, biocontainment guidelines and regulations, there appears to be a disconnect between awareness and implementation. The real question here is: How does the safety professional, whose job it is to ensure the safe working environment for all personnel, not only communicate the requirements, but also ensure that these principles are implemented? After all, they must often take the blame for safety problems in the organization.

**Do you have responsibility without authority?**

During the recent ABSA conference, I had a number of discussions with biosafety professionals who are frustrated that they can provide information on the regulations and guidelines to researchers, but have no real authority to ensure that those requirements are met. In many institutions, safety personnel do not report high enough in the organization to require compliance. They cannot “shut down” the research for lack of compliance because deans and department heads (in universities) and middle management personnel (in non-academic facilities) are supposedly responsible for making those decisions. However, leaving the decisions to these middle management personnel is actually a conflict of interest. Their job is to conduct research and source new grant monies. How can they be objective when judging the safety requirements? With all due respect, many of them are objective and perform appropriate risk assessments, but those that do not cause the problems such as those recently reported from Texas A&M.

It has been accepted that the individual responsible for compliance with the regulations and guidelines is the Chief Executive of the institution or company. Why then do health and safety personnel report to, or are overruled by, middle management with an agenda that may conflict with the insistence on compliance with safety rules?

It is time for safety professionals to educate the management of the institution that failure to provide a direct reporting structure to the top of the organization will in many instances result in a failure of the total safety program. Such a failure will result in adverse effects to the organization in terms of public perception or legal requirements. These adverse effects can include a loss of research funding, loss of accreditation and other equally debilitating problems.
The term “Safety Officer” carries with it the onus of a police state. I’ve never found that my dictating how something should be done has been acceptable to research personnel. Having said this, it is incumbent on the safety professionals to carefully evaluate their suggestions so that they are not requiring compliance in a way that is detrimental to the continuing operations of the organization. It is possible to work safely and efficiently at the same time. It is our responsibility as safety professionals to point out the requirements and then to work with the research personnel to develop safe, efficient methods to comply with those requirements. We are not in the lab doing the work and our job is to encourage laboratory personnel to understand the requirements and provide suggestions for procedures that meet those requirements. We can then evaluate their suggestions and provide them with guidance as to the safest procedures that should be implemented. Failure to develop a safe alternative method; however, should be reported to the top management of the organization so that appropriate action can be taken to protect personnel, the environment, and the organization.

It is my opinion that safe operation of any research facility begins with a top management that does the following: understands and accepts its responsibility for ensuring that personnel follow appropriate safety rules, is concerned and committed to safety operations, and requires close interaction between safety professionals and the research personnel. It is only with such an interactive program that we can ensure a safe working environment for our personnel and prevent unnecessary adverse publicity for the organization.

Biosafety Tips brings you practical approaches to biosafety or “news you can use.” If you are looking for a useful and sensible solution to a biocontainment problem, or perhaps a reference to help convince a skeptical researcher of the need for caution, this is the place to look. In this column, I share biosafety insights for managing a variety of workplace situations. I welcome feedback and suggestions for future topics. Please e-mail any comments or suggestions to karen_byers@dfci.harvard.edu or to Co-Editor Barbara Johnson at barbara_johnson@verizon.net.

Analysis of a Brucella Outbreak in a Veterinary Vaccine Manufacturing Plant

In a previous Biosafety Tips column (Volume 12, Number 3), the investigation of a Brucella outbreak in a clinical laboratory caused by streaking a slant on the open bench was described (Staszkiewicz, 1991). Another interesting and instructive outbreak of Brucella in a veterinary vaccine manufacturing plant was reported in the American Journal of Public Health (Olle-Goig, 1987). One hundred and sixty four staff members worked at the plant and were enrolled in a medical surveillance plan that included annual physicals conducted by the plant physician. The main building had a bacteriological laboratory and offices on the first floor, administrative offices on the second floor, an avian virology laboratory on the third floor, and the plant pharmacy, kitchen, and dining room were housed on the fourth floor. Separate, additional buildings were used for foot and mouth disease vaccine preparation, research, bottling, printing, and shipping. Four fresh-water wells supplied drinking and manufacturing water.

Outbreak Timeline

In August 1982, a few staff members returning from their annual four-week vacation were ill. The occupational health physician diagnosed Brucellosis. Additional cases were reported through the end of September; there were 22 clinically ill employees. A serological survey indicated another six staff had been exposed to Brucella; the total attack rate for staff was 17.1% (28/164). The mean incubation period before symptoms was 10 weeks with a range of five to 14 weeks.

Use of Attenuated Brucella

Vaccines against Brucella were manufactured on request, and Brucella vaccine was made from a live attenuated strain of Brucella melitensis, Rev-1, the first week in June. The plant closed on July 16 for the annual four-week vacation. It would be logical to assume that employees were exposed while handling the live Brucella vaccine. However, only five staff members worked in the bacteriological laboratory handling Brucella under an exhaust canopy, and only one of them became infected. Access to the laboratory was limited to the five bacteriological laboratory staff.