

BioSide Lines

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The Newsletter of the Office of Biological Safety, UW-Madison Safety Department
www.fpm.wisc.edu/biosafety

Transportation of Dangerous Goods

Scenario: You agreed in a moment of weakness to provide isolates to a colleague in Iowa. These are *Salmonella* variants collected as part of a recently completed clinical study, involving a very large number of small vials. The shipment requires almost a dozen infectious substance packages, but the good news is that coolant is not needed. FedEx has given you an estimate of \$500 to ship these packages. Your hourly worker, an LTE, wants to put in some extra hours and is willing to deliver the samples using the departmental fleet vehicle. Is this a legal and/or acceptable practice?

This practice is allowed under the Dangerous Goods Regulations because transportation of infectious substances by UW-Madison employees in an institutional vehicle does not meet the regulatory definition of transportation in commerce. The regulatory standard of care still applies and you should follow virtually all of the procedures that you would use when employing a commercial carrier. You would not need a dangerous goods declaration, nor would you use Chem-Tel for emergency response. The following steps should be used:

- 1) Use UN certified packaging that is appropriately marked and labeled.
- 2) Prepare an MSDS-equivalent for the pathogen that will accompany the shipment.
- 3) Train the worker about nature of the pathogen and emergency procedures.
- 4) Have an emergency response kit (e.g., absorbent, disinfectant, biohazard bags) in the vehicle.

OBS recommends against this cost-saving solution for this scenario but there are situations (e.g., transportation between buildings within the institution) where it would be impractical to hire a commercial carrier and where it can be done safely. We tend to think in terms of the worst case and potential exposures. In the scenario described above, it plays out like this: The vehicle is involved in a collision with a deer. The isolates are destroyed in the accident. The worker is severely injured, and as an LTE, is not covered by a health insurance plan.

When you use a commercial carrier to transport dangerous goods, you receive more service than just getting your isolates moved from point A to point B. You get a professional experienced carrier whose employer carries liability coverage. Feel free to call OBS to discuss best practices for "not-in-commerce" transport of infectious substances and other biological materials.

USDA-APHIS Permits

OBS requests copies of APHIS permits as part of the routine biosafety protocol review. The purpose is to facilitate compliance with the federal regulations and to provide guidance that may help you avoid some common issues.

A federal permit is required to receive certain plant and animal materials that could be detrimental to agriculture. Examples of regulated materials include plant and animal pathogens, biological control agents, noxious weeds, exotic organisms, and soil samples that might harbor a pathogen. This process is administered by the U.S. Department of Agriculture – Animal and Plant Health Inspection Service (APHIS). The plant materials are regulated by the Plant Pest Quarantine division of APHIS; animal materials by the National Center for Import and Export, Veterinary Services division. A permit is required when these materials are either imported into the country or moved between states. Intra-state movement is not within the purview of APHIS, but once it is received under a permit, the regulated material is subject to permit requirements until it is rendered nonviable.

The permits issued by APHIS are accompanied by specific conditions, which recently have become more stringent, and several are worthy of close attention. An important point that is a common permit condition is that the material may not be transferred to another facility without notification and prior approval from APHIS. Also, the permit must be renewed if the regulated material is retained beyond the permit's expiration date. Another common permit condition is that the shipping container must be decontaminated prior to disposal or re-use.

APHIS personnel may inspect the facility as a condition of approval for the initial permit and then again on a recurring (typically biannual) basis. In addition to the permit processing fee that is paid with the application, there may be a charge for the inspector's travel and preparation time in addition to an inspection fee.

These permits function like a contract between APHIS and the person requesting the regulated material. We ask the permit applicant to notify us that they are applying for a permit because APHIS usually does not inform us. A representative from the institution should be informed about scheduled inspections and afforded the opportunity to be present since general compliance issues may arise that require support and involvement of administration. Given sufficient notice of an inspection, staff from OBS will also visit the facility in advance to review the general requirements so that issues might be addressed. We can assist you in your efforts to meet the USDA's requirements.

Viral Vectors – Biosafety Protocol Required

Gene transfer via modified viruses has become increasingly common and viral vectors can be acquired as readily as a chemical reagent. Many of the viral constructs are replication defective, yet they can still enter cells, deliver genes of interest, and, in some cases revert to replication competency. Biosafety level 2 containment is appropriate for most viral vectors and this work is subject to the NIH Guidelines for Research Involving rDNA Molecules. Therefore, a biosafety protocol must be submitted prior to initiation of experiments that involve these reagents even if the experiments are considered low risk. You can either amend an existing protocol or write a new one. The protocol template is available at our website.

Incident response

“Hello, I just spilled ‘PathogenX’ on myself. What should I do now?” Questions like this used to routinely come to OBS. To help laboratory staff be better prepared to respond to an incident, we added a section in the biosafety protocol template on exposure response. Some investigators are unsure of the “right answer”.

Microbes in a laboratory setting have the opportunity to infect via unusual routes. For example, an organism that does not normally infect humans may be afforded an opportunity to do so when the natural barriers to infection are circumvented. All laboratory incidents should be reported to the supervisor. The Occupational Health Officer (263-2177) must be notified at the time of the exposure when there is a potential for impact on the employee's health. Don't wait for symptoms to develop. Notification of OBS is required for significant incidents; we will notify others (local, state, and federal officials), as required.

For incidents involving exposure to nonpathogenic microbes and for viruses for which there is no treatment, mitigate the exposure by washing the area well with soap and water. We recommend against washing a wound with bleach or scrubbing with an abrasive pad. For a mucosal exposure such as a splash to the eyes, flush with water for 15 minutes using a plumbed eye wash station. Eyewashes must be maintained by weekly flushing.

For research that involves use of a human or animal pathogen, the exposure response should be specific for the agent and include a medical evaluation. While physicians alone may prescribe antibiotics, laboratory personnel should know the susceptibility of their laboratory strains to antibiotics, since resistance may have been introduced through genetic engineering. Because laboratory exposures may involve organisms and chemicals that are uncommon, it is important to bring information, prepared in advance, to the treating physician about potential work-related exposures. At a minimum, bring a material data safety sheet to your physician. The UW Hospital Emergency Department can always serve as a starting point for a medical assessment or treatment

Shipping Infectious Substance and Other Biological Materials

The Office of Biological Safety will provide training and certification for shipping Infectious Substance and other biological materials, with a focus on safety and regulatory compliance for research laboratories. The Department of Transportation requires that persons involved in shipping hazardous materials in commerce be trained and certified in proper handling of these materials.

Friday, July 16, 2004
Union South 1:30 – 3:30 p.m.
Refreshments will be served.

Registration is required. Contact OBS at 263-2037 or biosafety@fpm.wisc.edu.

All staff are welcome to attend this class for initial or re-certification. Staff approaching their two-year expiration for certification will receive a notice in advance of that date. Computer-based training is available only for those who attended the class for their initial certification.

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