

BioSide Lines

July 2001

The Newsletter of the UW Office of Biological Safety

Criteria for Biosafety Protocol Submission:

Exempt Recombinant Techniques

The criteria for which the Office of Biological Safety (OBS) requests submission of a biosafety protocol are mostly easy to understand. A typical protocol includes more than one criterion and materials and methods requiring a mix of biosafety practices. Some of the work may be subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* while other aspects could be exempt. Of the following criteria, the one dealing with the *Guidelines* seems to be the least understood.

- Microbiological agents infectious to humans and/or animals; provide a copy of any required federal permit.
- Exotic plants, animals, and microbes (e.g., nonindigenous plant or insect pathogen, or biological control agent); provide a copy of any required federal permit.
- Animals, including their blood, tissues, and cell lines, for which a reasonable potential for transmission of zoonotic agents exists, e.g., wild-trapped animals, sheep, and rhesus macaques.
- Carcinogens, mutagens, drugs, and toxins when administered *in vivo* or *in vitro* to induce a biological outcome.
- Recombinant DNA molecules and recombinant DNA-containing organisms or cell cultures which are subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

Recombinant techniques are commonplace in modern biological research. The *Guidelines* provides the structure for oversight of these materials for assessment of appropriate containment and regulatory compliance. Recombinant DNA work can be subject to the *Guidelines* yet be considered low risk. There is a common misconception that low risk implies that the work also is exempt. The exemptions provided by the *Guidelines* are explicitly stated, but determining whether a particular aspect of recombinant work is exempt from or subject to the *Guidelines* can be a difficult exercise.

Work that is subject to the *Guidelines* may require little more than a notice, in the form of a biosafety protocol, to the Institutional Biosafety Committee, whereas other experiments require explicit approval prior to initiation. Work that is exempt from the *Guidelines*, however, may proceed without even a notice.

The *Guidelines* provides explicit exemptions for the following rDNA work:

- Work that is not in an organism, e.g., sequencing of DNA and polymerase chain reaction. (Section III-F-1)
- DNA propagated solely in the same species (Section III-F-3 and -4). Note that this exemption can not be used if elements of the construct such as promoters, enhancers, and marker traits are derived from another organism.
- Gene transfer between species known to exchange DNA by known physiological means (Section III-F-5, Appendix A).
- Less than 1/2 of any eukaryotic viral genome in tissue culture (Appendix C-I). Note that this exemption does not apply to genes derived from bacteria, fungi or parasites.
- Host vector systems using *E. coli* K-12, *Saccharomyces cerevisiae* and *S. uvarum*, *Bacillus subtilis* and *B. licheniformis* (Appendix C-II, C-III, C-IV), but there are exceptions to these exemptions.
- Work that does not present risk, as determined by the NIH Director (Section III-F-6). It is not sufficient for an investigator to declare that the research does not present a risk to humans, animals, or the environment. This decision is made by the NIH Director.

Most institutions require reporting of all recombinant work, and the biosafety staff then determines whether it is subject to the *Guidelines*. With our limited staffing, the UW Office of Biological Safety (OBS)

depends on investigators to make the preliminary assessment. The *Guidelines* are complex, so we offer assistance in making the determination.

Non-compliance with the *Guidelines*, such as not submitting a biosafety protocol for an experiment that is subject to the *Guidelines* even though it is a low risk activity, can jeopardize NIH funding for every investigator at this institution. Please contact the OBS (263-2037) if you have questions about how the *Guidelines* applies to your research. The *Guidelines* are available as a link from the UW biosafety website, www.fpm.wisc.edu/biosafety.

Laboratory Furniture

Just as all laboratory counters should be designed to be easily cleaned, laboratory chairs and stools should be covered with non-fabric material that is impervious to spills and can be easily decontaminated. During some recent lab visits, we observed fabric-covered lab chairs, pretty to look at and comfortable to sit on; this furniture is inappropriate where potentially hazardous chemicals, radioactive substances or biological materials are handled.

Appropriate laboratory furniture may be obtained from common laboratory supply vendors. Placing an order through UW Purchasing to a vendor under contract gives you a substantial discount over the catalog price and provides you strong protection if the product is defective. These prices, however, may still be substantially higher than local discount furniture stores. No matter where you choose to buy, be sure that you select impervious material and get a good warranty.

How to Comply with HazMat Shipping Regulations

Updated Instructions

Diagnostic specimens sent within the United States via Postal Service (USPS) have the requirement that the outer package must display the biohazard label. Contact OBS for the additional requirements that apply if you use USPS for international shipments of diagnostic specimens.

Infectious substances sent internationally via Postal Service may be sent or received only by institutions that have been granted prior permission. Please contact OBS to be covered by the registration application with the USPS International Business Unit.

Infectious Substance vs. Diagnostic Specimen Revisited. How should you classify clinical specimens presumed to harbor infectious but unidentified agents? This situation applies to samples taken from at-risk populations, which are suspected of harboring blood-borne pathogens. Unless preliminary testing has been done, there is no technical name to associate with the proper shipping name. The IATA DG specialists recommend that such materials be shipped as diagnostic specimens. A DG declaration is not needed, nor is UN certified packaging. Strict adherence to the package specifications of IATA packing instruction 650 for diagnostic specimens should provide sufficient protection against exposure should an accident occur in transit.

FX-12 is an IATA operator variation that only affects customers of Federal Express. Effective June 1, 2001, the shipper's declaration of dangerous goods must be typewritten or computer generated. FedEx allows certain but not all information to be handwritten. A generic DG declaration form that meets this requirement will be available soon at our website. A color printer is required to produce the red border. As with any DG declaration, it should be prepared and signed only by trained/certified staff.

Preservative solutions may be dangerous goods. Many chemical preservatives used for biological specimens are regulated as hazardous materials when transported, including ethanol and formalin/formaldehyde. Please contact OBS for function specific training on proper packaging, marking and documentation for these chemicals.

Pilots may refuse to accept Dangerous Goods. Pilots have final discretionary authority to bar materials from their airplanes. This right of refusal recently has affected infectious substances shipped

internationally via US Postal Service. You can do everything in accordance with the regulations and still have your package rejected!

Shipping Infectious Substances and Other Biological Materials

The Office of Biological Safety will provide training and certification for shipping infectious substances 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.

Monday, July 16, 2001
Union South 9 to 11 a.m.
Refreshments will be served.

Registration is required.

Contact Margy Lambert at 3-9013 or mlambert@fpm.wisc.edu.

Staff approaching their two-year expiration for certification will receive a notice in advance of that date. You are welcome to attend the class. Computer-based training is now available as an alternative, but only for those who have attended the class for their original certification.