FEATURE

Development of a policy to improve oversight of extremely hazardous chemicals

At the University of Nevada, Reno (UNR) the use of radioactive materials and biological agents in laboratory research requires approval by the institutional radiation safety committee and biosafety committee, respectively. Investigators who want to use hazardous chemicals, however, do not have to obtain approval. This disparity in institutional oversight of different classes of hazardous materials is a result of more stringent regulatory and research funding requirements rather than the hazards posed by the materials themselves.

Recognizing the potential for severe incidents involving highly reactive chemicals and other extremely hazardous chemicals, development of a policy for review of these chemicals was initiated. Development of this policy involved establishing the scope and inclusion criteria, consideration of the effect on laboratory research productivity, diplomacy, and compromise. Development of this policy in its current draft format is described.

By Ben Owens

HAZARDOUS MATERIALS ARE NOT VIEWED EQUALLY

Biological agents, chemicals, and radioactive materials are all classified as hazardous materials; however, the attitudes regarding these materials differ significantly, as do their level of regulation. Furthermore, the level of concern and regulation of these materials is often not commensurate with the risk that they represent.[1]

Radioactive materials are feared by some people and respected by most, and most researchers comply with the strict regulatory requirements that govern their use without question. Unlike biological agents and chemicals, use of radioactive materials has always been highly regulated. In research laboratories the use of radioactive materials is generally limited to tracer quantities which represent a risk much lower than that indicated by the Nuclear Regulatory Commission regulations that govern their acquisition and use. In the author's opinion, in most university research laboratories the risk associated with the use of radioisotopes is generally less than the risk associated with laboratory use of chemicals.

Historically, there have been few regulatory requirements that apply to the use of biological agents and safe work practices have generally been published as recommendations rather than regulations, with emphasis on assessment of risk to determine specific safe work requirements. For example, the CDC publication *Biosafety in Microbiological and Biomedical Laboratories* is generally regarded as the authoritative biosafety standard in the U.S.; however, this document is a direct regulatory standard only in the case of select agents, which are biological agents considered to be potential bioterrorism agents.[2] The scientific community has taken an active role in development and promotion of these recommendations, with the result being an emphasis on self-monitoring. In the early 1970s the development of recombinant DNA technology raised concerns about the creation of microorganisms with new pathogenic properties. Microbiologists recognized and acknowledged this potential, and in response, in 1975 organized the Asilomar Conference on Recombinant DNA Molecules where principles guiding laboratory use of recombinant DNA technology were established.[3] These principles subsequently led to the development of the *NIH Guidelines for Research Involving DNA Molecules*[4] (referred to as the NIH guidelines). More recent bioterrorism concerns have resulted in increased interest in the use of biological agents, which has led to the establishment of strict regulations that cover select agents.

Chemicals are commonly used in a wide variety of research activities ranging from chemistry to fields such as geography and anthropology. The education and skill of Principal Investigators (PIs) and other researchers using chemicals range from expert to little or no training in laboratory and chemical safety. The potential use of chemicals by researchers with a low level of specific expertise has generally not been a significant concern, with the prevailing attitude seeming to be that all researchers are sufficiently qualified and have the right to use chemicals.

INSTITUTIONAL OVERSIGHT OF HAZARDOUS MATERIALS

The level of institutional oversight of hazardous materials follows a similar pattern. Acquisition and use of radioactive materials is tightly controlled by Nuclear Regulatory Commission regulations. These regulations require institutions that use radioactive materials to obtain a license and use of

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1871-5532/$36.00
http://dx.doi.org/10.1016/j.jchas.2013.11.004

radioactive materials must be approved by an institutional radiation safety officer or radiation safety committee, depending on the type of institutional license.[5]

Use of recombinant DNA is guided by the NIH Guidelines. Although not regulation, institutions that accept NIH funding for research that involves recombinant DNA must agree to comply with the NIH Guidelines. One of stipulations of the NIH Guidelines is that each institution must establish an Institutional Biosafety Committee (IBC) that is responsible for approval of all research involving recombinant DNA. Many academic institutions have expanded the purview of the IBC to include approval of research involving all biological agents. Acquisition and use of select agents requires prior approval by the federal Select Agent Program and the naming of an institutional responsible official, who is responsible for approving acquisition and use of select agents and ensuring compliance with the select agent regulations.

There is no regulation that requires institutional review of the use of chemicals. The OSHA regulation, *Occupational Exposure to Hazardous Chemicals in Laboratories*,[6] requires that a chemical hygiene officer be appointed, with the stated role of this position being, "to provide technical guidance in the development and implementation of the provisions of the Chemical Hygiene Plan." There is no requirement for the chemical hygiene officer or an institutional committee to approve the use of hazardous chemicals, although the non-mandatory Appendix A of this regulation recommends that purchases of high risk chemicals be reviewed and approved by the chemical hygiene officer.

ESTABLISHING THE UNR LABORATORY SAFETY PROGRAM

The University of Nevada, Reno (UNR) laboratory safety program was established in the fall of 1997. It was recognized that there were instances where the risk associated with specific chemicals or chemical procedures justified review by persons other than the PI and researchers conducting the work; however, the implementation of basic laboratory safety program elements took precedence for several years.

Recognizing the need for faculty involvement and leadership in the laboratory safety program, the institutional Laboratory Safety Committee (LSC) was formed in 2003. The role of this committee is to provide guidance and expertise to the laboratory safety program, and to develop policies on laboratory safety issues. The committee consists of 5 faculty members from major academic departments that conduct laboratory teaching and research, and includes the chairs of the institutional radiation safety and biosafety committees, plus the EH&S chemical hygiene/biosafety officer. The scope of the committee includes chemical hygiene issues and broad safety-related issues that affect most campus laboratories. Oversight of the radiation safety program and biosafety program, and related specialty issues, is still provided by the institutional radiation safety committee and institutional biosafety committee, respectively.

The formation of the laboratory safety committee provided the mechanism to develop and implement a laboratory chemical review policy. Not only was the committee authorized by the university administration to fill this role but development of a policy by faculty members who were laboratory PIs themselves would likely increase its acceptance by campus researchers. Additionally, development of such a policy by a faculty committee would reduce the likelihood of the EH&S department being viewed as controlling chemical use or inhibiting laboratory research.

INITIAL POLICY DEVELOPMENT

When the idea of a chemical review policy was first proposed the LSC was reluctant to take action. While the committee acknowledged the lack of institutional oversight of chemical use relative to radioactive materials and biological agents, there was no regulation requiring the university to implement an institutional review procedure. Without a regulatory initiator the committee felt that acceptance by the faculty was unlikely, and therefore successful implementation of a policy would be very difficult. The committee's attitude changed as a result of a hallway conversation in which an engineering researcher asked if the EH&S department provided safety training for working with chemical explosives. It turned out that the engineering group was planning on synthesizing triacetone triperoxide, a high explosive commonly used for terrorist purposes. Review of the proposed work revealed that the researchers did not have training and experience in performing this kind of work and ultimately the researchers elected not to attempt this synthesis. This event demonstrated to the committee that there were situations where review of chemical work beyond that of the researchers involved in the project was justified and led to the decision to develop a policy requiring institutional review of certain laboratory chemicals.

The committee decided to limit the policy to review of those chemicals that represented an extreme acute hazard, which either due to toxicity or reactivity could produce significant harm as the result of a single incident. The committee felt that these chemicals, to be referred to as extremely hazardous chemicals, were of most concern, and therefore, their review would be more readily accepted by laboratory investigators. Additionally, it was thought that use of these extremely hazardous chemicals would be relatively infrequent and would represent a manageable workload for reviewers and would not generally inhibit research productivity.

With regard to toxicity, the primary route of exposure to be considered was inhalation. After extensive review of inhalation toxicity criteria and evaluation of the campus chemical inventory it was ultimately decided to adopt the Globally Harmonized System category 1 acute hazard definition for inhalation of gases and vapors. For gases, the criterion is a median lethal concentration (LC_{50}) of less than or equal to 100 parts per million by volume (ppm), and