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"Safety Comes First"

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Making International Shipments: What CWRU Shippers Need to Do

In the June/July 2014 issue of this newsletter, readers learned that federal export control regulations can apply when regulated items are being shipped abroad. Before shipping a device, materials, or other items abroad, a CWRU employee trained in export compliance must determine whether an export license, or any other form of federal authorization, is needed prior to making the shipment. These are the steps that all CWRU researchers should follow when planning to make an outgoing international shipment of items or materials:

1. The CWRU Principal Investigator works with the CWRU Technology Transfer Office to determine whether a Material Transfer Agreement ("MTA") is needed prior to the shipment. The CWRU PI initiates this by submitting a completed MTA Review Form found at https://research.case.edu/forms.cfm#tech_mgt.

2. If the Technology Transfer Office ("TTO") determines that an MTA is needed between CWRU and the overseas organization to receive the items or materials, the Principal Investigator and TTO work together to put it in place. Once the MTA is completed and signed by CWRU and the recipient organization, the Technology Transfer Office will forward a copy of the final contract to the PI. The PI should keep a copy of the final MTA for easy reference. Note that MTAs not only help to ensure compliance with the federal export laws, but they also protect investigators' intellectual property rights.

3. Before making the shipment overseas, the PI should contact the CWRU Environmental Health and Safety Office. This step is necessary so that the Environmental Health and Safety Office can analyze the contents of the shipment in light of the export regulations and determine whether the shipment can proceed immediately, or whether federal pre-authorization is needed. If the Technology Transfer Office determined that an MTA was needed, then the PI should provide Environmental Health and Safety with a copy of the signed MTA so that it can match the requested shipment with the formal contract.

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Liability in the Lab: UCLA Case Sends a Signal to Universities

"Prosecutors offered evidence that she was given little training and no protective lab coat."

Prosecutors in Los Angeles reached a plea agreement in their criminal case against a University of California chemistry professor over the accidental death of a student researcher, putting an opaque ending on a landmark legal pursuit credited with pushing lab-safety improvements on university campuses nationwide.

The UCLA professor, Patrick G. Harran, accepted penalties that include 800 hours of community service and the threat of resumed legal proceedings in the event of new lab-safety violations over the next five years, but no jail time. The settlement and the likely avoidance of a trial, five years after the accident that killed Sheharbano (Sheri) Sangji and two years after criminal charges were filed, left the victim's family deeply disappointed. "A trial would have brought about serious change, overnight, that a settlement really cannot achieve," said Ms. Sangji's sister, Naveen F. Sangji, a general-surgery resident at Massachusetts General Hospital who has served as a family spokeswoman. Independent safety advocates, however, were considerably less pessimistic about the ultimate effect of the case. Several agreed that universities' research laboratories still remain more dangerous than their corporate counterparts. Yet they also expressed confidence that the impetus for improvement brought by the first filing ever of criminal charges over a fatal university lab accident has not been diluted by the plea bargain. "It's not an insignificant penalty that he's paying," said James A. Kaufman, a retired chemistry professor who heads a lab-safety training institute. The case was felt deeply across academe, said Nathan P. Watson, whose company provides lab-research-management services, and "I don't think the effect has all been lost."

Inexperienced and Unprotected

Mr. Harran, who is now 44, heads a UCLA laboratory that explores disease-fighting properties in naturally occurring molecules. Sheharbano Sangji was 23 when she was badly burned in the lab on December 29, 2008. The accident occurred as she handled a syringe containing *tert*-butyllithium, a compound that ignites spontaneously in air. Ms. Sangji was relatively inexperienced and was wearing a synthetic-fiber sweatshirt that burned quickly. Prosecutors offered evidence that she was given little training and no protective lab coat. She died of her injuries 18 days later in a specialized burn center. Naveen Sangji repeatedly flew to Los Angeles in the years after the accident to help press the legal case against both Mr. Harran and the University of California. Judge Shelly B. Torrealba of the Superior Court of California in Los Angeles approved a deal in July 2012 that ended charges against the university in return for its adopting new lab-safety measures and establishing a $500,000 scholarship in the name of Sheharbano Sangji. Another judge in the same court, George G. Lomeli, accepted the legal settlement with Mr. Harran, who faced up to 4.5 years in prison if tried and convicted on the charges brought against him. Mr. Harran has avoided any public comment in the case. After Naveen Sangji made a 50-

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Liability in the Lab: UCLA Case, cont.

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minute presentation on the impact of her sister's death on her family, the judge doubled the prosecution's suggestion of 400 hours of community service. The most serious penalty facing Mr. Harran, however, appears to be the need to avoid any lab-safety violations for five years, with quarterly reports to the court by state safety inspectors. Under that pressure, "he has an extremely tough row to hoe over the next five years," said Neal R. Langerman, a former associate professor of chemistry at Utah State University who now heads Advanced Chemical Safety, a consulting firm. The family disagrees, seeing it as "a fairly easy agreement to comply with," Naveen Sangji said. But Mr. Kaufman, Mr. Watson, Mr. Langerman, and other safety experts said criminal pursuit of Mr. Harran had already achieved about as much as could be reasonably expected from the legal system in terms of forcing change on university campuses.

Holding Universities Responsible

The key now, said Janet D. Stemwedel of San Jose State University, is for universities and their financial backers to shift the expectation of safety from individuals to departments and entire organizations. Universities could do that through rules that include barring departments with poor safety records from accepting new graduate students, said Ms. Stemwedel, an associate professor of philosophy with a doctorate in physical chemistry who studies research practices. Mr. Kaufman suggested going a step further by holding the organizational head, such as a university president, legally liable for fatal lab accidents. Employees who don't get on board should be fired, said Mr. Kaufman, a retired professor of chemistry at Curry College who now serves as president and chief executive officer of the Laboratory Safety Institute. "That's harsh talk, and academic institutions don't like it," he said, "but the places that have the best safety programs make working safely a condition of employment." Mr. Watson, president and chief executive officer at BioRAFT, which provides laboratory-management services, said he sees the process of improving university lab safety as a series of stages, beginning with formal acts of compliance and liability mitigation. The Harran case helped get most universities to that first stage, but it has left most of them short of fully embracing the necessary deep changes in cultural attitudes, he said. The progression of universities into more meaningful stages is likely to continue, Mr. Watson said. And a jail sentence for Mr. Harran might have even slowed the process, he said, by creating a reaction on campuses that focused more on questions of justice than on the need to deal with their own institutional behaviors.

Continued incidents such as the death of a technician in an explosion in a petroleum-engineering lab on the Texas A&M University campus in Qatar, and a science-lab explosion that injured a University of Minnesota graduate student in Minneapolis, show the need for improvement remains deep, Mr. Langerman said. At the same

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"The key now…is for universities and their financial backers to shift the expectation of safety from individuals to departments and entire organiza-tions."

RADUCATION – Radiation Basics

"All radio-active atoms are un-stable..."

1. What is an Atom?

All matter, which is everything that exists, is made up of atoms. Atoms are very, very small and made up of protons and neutrons clustered in a nucleus at the center, surrounded by a cloud of electrons orbiting around the outside. Atoms make up elements, like oxygen, hydrogen, and potassium. The number of protons found in the nucleus determines the element. An atom may have an electrical charge, just like a battery. The protons in the nucleus have a positive (+) charge and the orbiting electrons have a negative (-) charge. The neutrons in the nucleus have no charge. If the number of protons in an atom equals the number of surrounding electrons, then the amount of positive charge in the atom would equal the amount of negative charge, resulting in an atom with a neutral charge. In some cases an atom of an element may have more or less neutrons than protons in the nucleus. When the number of protons remains the same, but the number of neutrons is different, we call these isotopes of the same element. Isotopes are generally referred to by the element name and a number, based on the total number of protons and electrons present. To explain this, we will use the element carbon. The number of protons in a nucleus determines an element's atomic number. All atoms of carbon have six protons in the nucleus, so the atomic number for carbon is "6". In the most common form of carbon, there are also six neutrons. If you add together the number of protons and neutrons, you get the number of the carbon isotope, which in this case would be carbon-12. Other isotopes of carbon will have a different number of neutrons in the nucleus. Another common carbon isotope, with eight neutrons and six protons, is called carbon-14, and is a radioactive isotope of this element.

2. How Does an Atom Give Off (Emit) Radiation?

If an atom is not stable (unstable) it has too much energy to remain in its current form. All radioactive atoms are unstable, and will give off, or emit, this extra energy through various methods, eventually becoming a stable atom. When a radioactive atom is giving off energy it is said to be going through radioactive decay. How long this decay process may take depends on the type of radioactive atom. The energy given up by the nucleus of a radioactive atom may cause one or more electrons to be "kicked" out of their orbit around an atom. When this happens there will be a negatively- charged electron floating by itself, and an atom with a positive charge, also called an ion, due to the loss of the electron. The energy from a radioactive atom that causes the formation of ions is called ionizing radiation.

3. What are the Three Primary Types of Radiation?

Ionizing radiation is generally found in one of three forms – alpha particles, beta particles, or gamma rays.

Alpha particles are made up to 2 neutrons and 2 protons and are essentially a

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RADUCATION – Radiation Basics, cont.

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small nucleus with no orbiting electrons and a positive charge. Because alpha particles are fairly large (at least in atomic terms) they will interact with more atoms and use up their energy creating ions over a very short distance (again, in atomic terms). Because of these characteristics, an alpha particle may be stopped by something as thin as a sheet of paper or layer of cloth.

A beta particle is an electron created from the decay of a neutron and then ejected from the nucleus. It is extremely small and much lighter than an alpha particle. A beta particle typically contains more energy and will travel further than alpha particles through solid materials. Beta particles are usually stopped using sheets of plastic or Lucite.

Gamma radiation is different from alpha and beta because it is not a particle; gamma radiation is a ray of energy, similar to visible or ultraviolet light, but containing much higher energy levels. Depending on their energy level, gamma rays may be stopped by various thicknesses of lead, concrete, or soil. X-rays used in dental and medical procedures are similar to gamma rays.

4. How is Radiation Used?

Radiation from radioactive materials or radiation-generating equipment (x-rays) is used in a wide range of commercial, medical, and research procedures and processes.

Commercial and Industrial Uses-Radiation may be easily detected because of the energy that it contains. This trait makes it useful in measuring thicknesses, volumes, flow rates, densities, and contaminant levels. If a radiation source and an appropriate detector are set up together, anything that passes between the two will cause a change in the amount of radiation received by the detector. Analyzing this change will allow the user to know if their process is operating properly. Two common consumer products contain very small quantities of radioactive material used to perform their very useful functions. Many smoke detectors contain the isotope americium-241 in the detection portion of the device. Another widespread commercial use of radiation is in building exit signs which contain radioactive hydrogen-3, also called tritium. The fluorescent properties of tritium allow the exit signs to remain illuminated during a power outage. Radiation in very large quantities is used as a sterilization method. The energy released by the gamma radiation as it passes through the product being sterilized is what "performs" the sterilization. The radioactive material used to produce the gamma radiation never comes in contact with the materials being sterilized. This can be a useful alternative when chemical sterilization may actually contaminate the product being treated, such as cosmetics, contact lens solutions, and many medical supplies. Radiation is also routinely used to sterilize bulk quantities of spices and some grains.

Medical Uses-Radiology is the common term for the use of radiation in the diagnosis and treatment of disease. Radiology not only refers to the medical use of x-ray devices, but also to

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"The fluorescent properties of tritium allow the exit signs to remain illuminated during a power outage."

Bloodborne Pathogen Standard

"Employers must update the plan [ECP] annually to reflect changes in tasks, procedures, and positions that affect occupational exposure..."

Bloodborne pathogens are infectious microorganisms present in blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), the virus that causes AIDS. Workers exposed to bloodborne pathogens are at risk for serious or life-threatening illnesses.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; the teletypewriter (TTY) number is (877) 889-5627.

Protections Provided by OSHA's Bloodborne Pathogens Standard

All of the requirements of OSHA's Bloodborne Pathogens standard can be found in Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030. The standard's requirements state what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials (OPIM), as defined in the standard. That is, the standard protects workers who can reasonably be anticipated to come into contact with blood or OPIM as a result of doing their job duties. In general, the standard requires employers to:

Establish an exposure control plan. This is a written plan to eliminate or minimize occupational exposures. The employer must prepare an exposure determination that contains a list of job classifications in which all workers have occupational exposure and a list of job classifications in which some workers have occupational exposure, along with a list of the tasks and procedures performed by those workers that result in their exposure.

Employers must update the plan annually to reflect changes in tasks, procedures, and positions that affect occupational exposure, and also technological changes that eliminate or reduce occupational exposure. In addition, employers must annually document in the plan that they have considered and begun using appropriate, commercially-available effective safer medical devices designed to eliminate or minimize occupational exposure. Employers must also document that they have solicited input from frontline workers in identifying, evaluating, and selecting effective engineering and work practice controls.

Implement the use of universal precautions (treating all human blood and OPIM as

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Bloodborne Pathogen Standard, cont.

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if known to be infectious for bloodborne pathogens).

Identify and use engineering controls. These are devices that isolate or remove the bloodborne pathogens hazard from the workplace. They include sharps disposal containers, self-sheathing needles, and safer medical devices, such as sharps with engineered sharps-injury protection and needleless systems.

Identify and ensure the use of work practice controls. These are practices that reduce the possibility of exposure by changing the way a task is performed, such as appropriate practices for handling and disposing of contaminated sharps, handling specimens, handling laundry, and cleaning contaminated surfaces and items.

Provide personal protective equipment (PPE), such as gloves, gowns, eye protection, and masks. Employers must clean, repair, and replace this equipment as needed. Provision, maintenance, repair and replacement are at no cost to the worker.

Make available hepatitis B vaccinations to all workers with occupational exposure. This vaccination must be offered after the worker has received the required bloodborne pathogens training and within 10 days of initial assignment to a job with occupational exposure.

Make available post-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident. An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM. This evaluation and follow-up must be at no cost to the worker and includes documenting the route(s) of exposure and the circumstances under which the exposure incident occurred; identifying and testing the source individual for HBV and HIV infectivity, if the source individual consents or the law does not require consent; collecting and testing the exposed worker's blood, if the worker consents; offering post exposure prophylaxis; offering counseling; and evaluating reported illnesses. The healthcare professional will provide a limited written opinion to the employer and all diagnoses must remain confidential.

Use labels and signs to communicate hazards. Warning labels must be affixed to containers of regulated waste; containers of contaminated reusable sharps; refrigerators and freezers containing blood or OPIM; other containers used to store, transport, or ship blood or OPIM; contaminated equipment that is being shipped or

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"An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM."

Bloodborne Pathogen Standard, cont.

"Employers must ensure that their workers receive regular training that covers all elements of the standard ..."

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serviced; and bags or containers of contaminated laundry, except as provided in the standard. Facilities may use red bags or red containers instead of labels. In HIV and HBV research laboratories and production facilities, signs must be posted at all access doors when OPIM or infected animals are present in the work area or containment module.

Provide information and training to workers. Employers must ensure that their workers receive regular training that covers all elements of the standard including, but not limited to: information on bloodborne pathogens and diseases, methods used to control occupational exposure, hepatitis B vaccine, and medical evaluation and post-exposure follow-up procedures. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Also, HIV and HBV laboratory and production facility workers must receive specialized initial training, in addition to the training provided to all workers with occupational exposure. Workers must have the opportunity to ask the trainer questions. Also, training must be presented at an educational level and in a language that workers understand.

Maintain worker medical and training records.
The employer also must maintain a sharps injury log, unless it is exempt under Part 1904 -- Recording and reporting Occupational Injuries and Illnesses, in Title 29 of the Code of Federal Regulations.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html. To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call us toll-free at **(800) 321-OSHA (6742)**. Occupational Safety and Health Administration www.osha.gov 1-800-321-6742. **For assistance, contact us. We can help. It's confidential.**

Liability in the Lab:, cont.

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time, the action by California prosecutors "has gotten the attention of virtually every research chemist out there," even in states that may seem more reluctant to pursue such cases, he said. "This is precedent-setting, and now that the precedent is set, you really do not want to test the water, because the water is already boiling." Naveen Sangji isn't so sure. "We just hope that other young people—researchers, students, scientists—are safer in the future than Sheri was," she said.

By Paul Basken
Chronicle of Higher Education

Making International Shipments, cont.

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If you have questions regarding Material Transfer Agreements (MTAs), please contact Andrew Jarrell in the Technology Transfer Office, andrew.jarrell@case.edu, 368-1401.

If you have questions on how the export regulations impact specific international shipments, contact Lisa Palazzo, Director of Export Control and Privacy Management, at 368-5791, or Boyd Kumher, University Chief Compliance, Export Control and Privacy Management Officer, at 368-0833; or email exportcontrol@case.edu . For more information on the export control regulations, including the full text of CWRU's Export Control Policy Statement, visit www.case.edu/compliance/exportcontrol/.

"If you have questions regarding Material Transfer Agreements (MTAs), contact Andrew Jarrell in the Technology Transfer Office. "

RADUCATION – Radiation Basics, cont

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the practice of nuclear medicine, which uses various radioactive materials and procedures for patients with such diverse problems as cardiac disease, thyroid disorders, respiratory problems, and some forms of cancer. Some laboratory tests use radioactive materials in the analysis of blood and various other body fluids and tissues.

Research-Radiation use has increased significantly in the area of research. Radioactive materials are used in the development of many new products, including fertilizers, pesticides, and chemical products. A common use in research is carbon dating, which allows researchers to determine the age of an item - such as mummified remains or a prehistoric skeleton - by measuring the amount of radioactive carbon-14 present in the sample. Measuring the amount of radioactive material in soil and rocks allows geologists to determine whether valuable minerals might be present.

5. How is Radiation Use Regulated in Ohio?
The Ohio Department of Health (ODH) is the agency responsible for oversight of the many medical, academic, industrial and research uses of radioactive materials and radiation-generating equipment in Ohio.

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