KGI KECK GRADUATE INSTITUTE

POLICY 532

Shipping and Receiving Hazardous Materials

See also PRO 532 and Form532: Request to Ship Hazardous Materials

Responsible Officer: Dean of Research | Approved By: President's Cabinet

Effective Date: July 27, 2015

Purpose

The use of hazardous materials is an integral part of research at Keck Graduate Institute (KGI). At times, it is necessary to ship these materials to a colleague, another research facility, or back to the manufacturer. Hazardous materials may include items such as: chemicals (including research samples), biological materials (including infectious agents, dry ice, genetically modified micro-organisms, or diagnostic specimens). However, shipping chemical and biological material is not as simple as putting postage on a package and dropping it in the mailbox.

KGI requires that any hazardous material leaving campus to be subject to and compliant with several administrative and regulatory requirements. Laboratory Safety Office has been fully trained to handle shipment of most, if not all, hazardous materials and is designated as the one central hazardous material shipping center for KGI. While the process may be involved and lengthy, especially the first time, it is only by following all the rules that KGI can ensure that material arrives where we want it, on time, and without being subjected to delay, fines or other penalties.

Policy

Background and Regulatory Entities

The U.S. Department of Transportation (DOT) is the Federal agency given the authority by Congress to regulate the safe transportation of hazardous materials in intrastate, interstate, and foreign commerce. This authority was granted in the Hazardous Materials Transportation Act (HMTA), first adopted in 1974 and amended in November 1990 as the Hazardous Materials Transportation Uniform Safety Act of 1990 (HMTUSA).

In response to this mandate, the DOT has built up a body of rules called the Hazardous Materials Regulations (HMR). HMRs are contained in Title 49 of the Code of Federal Regulations (CFR), Parts 171–180. The primary modes of transportation governed by 49 CFR are rail and truck.

If a shipment of hazardous materials is made by air, the governing regulations are those of the International Civil Aviation Organization (ICAO). These are published by an association of air carriers known as the International Air Transportation Association (IATA). Domestic air shipments are governed by the IATA Dangerous Goods Regulations as well.

If hazardous materials are shipped by vessel, the governing regulations are those published by the International Maritime Organization (IMO) under its set of regulations known as the International Maritime Dangerous Goods Code (IMDG). Hazardous materials shipments prepared for export under the IMDG Code may move within the United States to and from the port of exportation even though the materials may not be regulated under 49 CFR.

More information on regulatory entities can be found at phmsa.dot.gov.

Regulated Parties

There are three regulated "entities" subject to the hazardous materials regulations (HMR):

1. Shipper/receiver
2. Carrier or Transporter
3. Container manufacturer

The terms "shipper" and "receiver" are undefined in the regulations. Instead, DOT prefers to apply the regulations to "any person" who offers or accepts a hazardous material for transportation. In this way, it invalidates the issue of ownership,so that one doesn't have to "own" a material to be the shipper or receiver. Any person performing the functions of a shipper or receiver is recognized as the shipper/receiver under 49 CFR and is subject to all of the "shipper requirements" HMR.

Penalties for Non-compliance

Failure to comply with this policy and federal regulation are extremely serious. In the event that inspection of KGI's hazardous materials operations discloses violations of the hazardous materials regulations, KGI and the individual "shipper" may be subject to civil and/or criminal penalties. A person who knowingly violates the Federal hazardous material transportation laws can be fined, imprisoned, or both. Monetary fines can range from $450 for training and up to $32,500 per day of offense for civil fines, a maximum of $500,000 and/or up to five years in prison for criminal violations. In almost all instances, these shipper inspections are unannounced.

Shipping Hazardous Material

When hazardous materials are offered for transport by a commercial carrier like FedEX or UPS, the shipment becomes regulated by the U.S. Department of Transportation (USDOT) and/or international agencies (IATA, ICAO). To comply with shipping regulations, hazardous materials must be properly classified, packaged, documented, and handled by trained employees. Failure to meet these requirements may result in delays, loss of research samples, and potential regulatory fines.

Shipping personnel must have specialized training and ensure specific packages, labels, and paperwork are properly used. Therefore, Laboratory Safety has been designated as the one central hazardous material shipping center for KGI. Lab Safety staff are fully trained and have materials to handle shipment of most, if not all, hazardous materials. Please ensure any hazardous materials you need to ship off campus through a public contractor are coordinated through Laboratory Safety.

The Principal Investigator (PI) is responsible for the following costs: proper packaging materials, dry ice (if applicable), and shipping costs. The PI is also responsible for providing the information necessary for the KGI shipper to determine the proper hazardous materials classification, packaging, and documentation. Materials sent to Laboratory Safety for shipment will be rejected if the proper information is not sent with the materials to be shipped. Please follow the procedures as described below.

For additional information, visit fmcsa.dot.gov/regulations/hazardous-materials/how-comply-federal-hazardous-materials-regulations.

A Material Transfer Agreement May Be Required

A Material Transfer Agreement (MTA) is a legal contract between two entities which specifies that materials are to be used for scientific work only and not for commercial use and defines the rights of the parties. MTAs are executed between a company and Keck Graduate Institute, not between individuals.

You will need an MTA if any of the following apply:

- Your research sponsor requires it
- You received the original material via an MTA
- The material is covered under the USA PATRIOT Act or the Centers for Disease Control List of Selected Agents (visit selectagents.gov)
- Your outgoing material has IP protection or may become protected
- The receiving agency requires an MTA

You may not need an MTA if you are returning material to a supplier, or you are providing product(s) to a project sponsor that are otherwise covered by a confidentiality agreement.

If you need an MTA, or are unsure whether an MTA is needed, complete an MTA request by contacting the Secretary to the Board of Trustees.

Export Review For All Materials Leaving The U.S.

An export review must be completed if the shipment is leaving the country. Please contact KGI's Office of Research & Sponsored Projects to determine if the shipment is regulated by export review.

Foreign Customs

In many instances, following the above procedures and coordination with the carrier will preclude problems at the foreign point of entry. However, customs officials may impose unexpected obstacles. Both you and the recipient should be prepared for delays and the possibility of having to provide additional information. Contact KGI's Office of Research & Sponsored Projects to with any questions regarding customs.

Shipment Of Virgin (Stock) Chemicals

KGI Laboratories should not rely on KGI's Laboratory Safety shippers for shipment of the virgin stock chemicals used to support their research activities at off campus locations. It is almost always more cost-effective and efficient to have lab/research supplies delivered directly to the location at which they will be used. Advance planning and coordination with the off-site location will make this feasible in most instances.

CONTACTS

- Lab Safety: Jasmine Yu, jasmine_yu@kgi.edu, 909.607.8698
- Office of Research & Sponsored Projects: orsp@kgi.edu, 909.607.9313

PRO 532A

Shipping Procedures for Hazardous Materials

Action By	Action
PI/researcher	1. Emails jasmine_yu@kgi.edu one week prior to a planned shipdate to receive a Request to Ship Hazardous Material Form attached to this procedure. This form is required for all shipments. 2. Completes the form concerning the material for shipment. Sends the completed form via email back to Lab Safety for approval.
La Safety Officer	3. Approves paperwork, contacts PI, and directs PI to bring materials to be checked against the information provided in the request form. Materials will not be approved for shipping if the Request to Ship Hazardous Material Form is incomplete at the time of delivery. 4. Advises PI whether export controls review or MTA is needed. (See below). *Note: Lab Safety will not allow shipment of any item that it believes may require an MTA or Export Control review until it has received approval from the appropriate offices.*
PI/researcher	5. Obtains signed MTA from ORSR prior to shipping, if needed. 6. Brings materials to Lab Safety to be checked against the information provided in the request form. 7. Delivers packaged materials to shipping (or other designated person may deliver).
Shipping	8. Receives deliveries and ships materials from KGI Building 535, Room 116. • If the materials have been approved and ready for shipment before 10 a.m., they will be shipped the same day. • If material is processed and approved after 10 a.m. it will be shipped the following day. • Shipments received or verified after 10 a.m. on Friday morning will be shipped the following Monday. 9. Notifies PI/researcher when package has shipped, with a tracking number of the materials.
PI	10. If shipping is not available, takes material back to lab for proper storage; contacts Lab Safety concerning the shipment of the material the next normal working day.

PRO 532B

Receiving Hazardous Materials

Before requesting hazardous material to be shipping to KGI, please review the following.

Action By	Action
PI/researcher	1. Obtains current Institutional Biosafety Committee (526POLICY) approval to work with the material if it requires Biosafety Level 2 or higher precautions or is a biologically-derived toxin. 2. Obtains any required permits, and sends copies to the shipper. Visit phmsa.dot.gov/approvals-and-permits/hazmat/hazardous-materials-approvals-and-permits-overview. 3. If the shipment is from a foreign country, checks whether shipperis are aware of U.S. shipping regulations and has the correctlabels, and sends labels to the foreign shipper if needed. For questions regarding foreign shipping regulations, contact Kirsten_Torguson@kgi.edu. 4. Notifies Laboratory Safety and Shipping when the shipment will be arriving so that Lab Safety staff is present to receive and inspect the material when it arrives. 5. Notifies Laboratory Safety to add Biosafety Level 2 or higher organisms and biologically-derived toxins to the university's biological material inventory.
Shipping	6. Promptly notifies PI and Lab Safety when shipment is received.
Lab Safety Officer	7. Receives, Inspects, and Accepts Shipment 8. Adds Biosafety Level 2 or higher organisms and biologically-derived toxins to the university's biological material inventory.

FORM 532

Request to Ship Hazardous Materials

Please submit this form to Laboratory Safety if you plan to ship anything that may be a regulated Hazardous Material (HM). Complete and attach the form as a word document and email jasmine_yu@kgi.edu at least one week prior to when you want material shipped. Laboratory Safety will review the completed form and reply with an approval to ship or a request for additional information.

If approved, Laboratory Safety will complete the shipping papers, provide proper labels, shipping containers, and arrange for pickup of the package. You will be notified when package has shipped.

Please complete each question and provide an answer, including N/A if applicable, to facilitate the review process. Improper or missing paperwork and/or packaging may result in delays. All shipments of hazardous materials require a Safety Data Sheet (SDS). This is true even for "small" amounts and newly created products/samples. If there is no commercial SDS, you must create one to the best of your ability and knowledge of the chemical/biological components. Department of Transportation (DOT) Dangerous Goods and Export Controlled Items need additional time to be processed, so plan in advance for these shipments.

For additional information, visit fmcsa.dot.gov/regulations/hazardous-materials/how-comply-federal-hazardous-materials-regulations.

Contact Information

Requesters (Consignor)

Name:

Faculty Contact:

Organization:

Department:

Street Address:

Lab/Bldg #:

City, State, Zip:

Country:

Email Address:

Phone:

PI Signature:

Monetary Value:
(if blank then $0.00 will be assumed)

Recipient (Consignee)

Name:

Faculty Contact:

Organization:

Department:

Street Address:

Lab/Bldg #:

City, State, Zip:

Country:

Email Address:

Phone:

PI Signature:

Monetary Value:
(if blank then $0.00 will be assumed)

Shipment Details

Please note: International shipments of hazardous materials may require special approvals and additional paperwork, and in addition to Laboratory Safety, will require the involvement of the Office of Sponsored Research with staff who oversee exports, and that may take a lot of time. Plan accordingly. Laboratory Safety provides packaging materials and packs shipment, but charges back for the materials cost. Shipper must provide cold packs or dry ice, when required.

1. Please provide the appropriate storage conditions while materials are waiting for completion of paperwork. (e.g. RT,4C, -20C or dry ice)
2. When do you want to ship the material?
3. What conveyance method would you like to use to ship the material? (US Postal Service, FedEx, other).
4. Delivery Preference: Priority Overnight, etc.
5. If using recipient's account number, please provide here:
6. What is the source of biological material, i.e. ATCC or patient specimen, list source?

Will this shipment include dry ice?	Yes	No
Does the recipient plan to only use the material at their institution for research purposes? If "no", list intended purpose:	Yes	No
Will the material be distributed to any other location beyond its destination?	Yes	No
Are the above products available commercially to the recipient?	Yes	No
Is this a process that is likely to be repeated, with the same (or basically the same) materials, packaging, recipient, etc.?	Yes	No
Are you shipping internationally? If yes, you need to contact Kirsten Torguson at kirsten_torguson@kgi.edu prior to shipping.	Yes	No
Does the PI have/require a material transfer agreement to send this to the recipient? If unsure, contact orsp@kgi.edu.	Yes	No
If you answered "Yes" to the above, does it allow transfer to another party? If unsure, contact orsp@kgi.edu.	Yes	No

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For Biological Materials

1. What is the material (e.g., viable microorganism, DNA, blood, genetically modified microorganism, toxin, etc.)? Clearly indicate at least one detailed name for the material.
2. What was the source agent or organism the product was isolated from?
3. What is the quantity of material to be shipped?
4. What is the number of containers and amount of material to be shipped? (e.g. 1x50ml)

Is the organism a known:

Human pathogen?	Yes	No
Animal pathogen?	Yes	No
Plant pathogen?	Yes	No
Toxin? (list LD50 if known)	Yes	No
Is the organism genetically modified or altered?	Yes	No
Do the contents contain any pathogens, viruses, or anything harmful to humans or animals? If yes, specify:	Yes	No
Are there any other hazardous materials (ethanol, formaldehyde, etc) included with this shipment in addition to the biological material? (list)	Yes	No
Is the nucleic acid sequence in itself or through its transcribed or translated products able to represent a significant hazard to human, animal or plant health?	Yes	No
Can the nucleic acid sequence in itself or through its transcribed or translated products enhance another organism into which it may be inserted or otherwise integrated, to cause serious harm to human, animal or plant health? If yes explain	Yes	No
Are there any stability or degradation concerns about the material? Yes No (if Yes, state reasons for concern below)	Yes	No

For Chemical Materials

1. Clearly describe the contents of each container (vial) being shipped. Include state (solid, liquid, gas) and quantity (by weight or volume).
2. Type of container material is in (glass bottle, plastic bottle, metal can, etc.) Please describe:
3. What are the known hazardous properties of the material? (e.g. Corrosive, reactive, toxic, flammable, oxidizer, if unknown write “unknown”, if non-hazardous indicate “non-hazardous”)
4. Manufacturer/Vendor/Distributor please list:
5. Does the material have a Chemical Abstract number (CAS)? (If yes please provide the number)

For All Materials

1. Do you have any reason to suspect that exposure (inhalation, skin exposure, ingestion, etc.) to any of the material being shipped could be harmful to an individual or the environment (other animals, etc.)?
2. Provide links to any known SDS or toxicology information. If you do not have any health hazard information, reply “None.” Note that “non-hazardous”material still needs reference to hazard information.
3. Do you need a shipping box from Laboratory Safety?
4. If yes, what account to charge box to:

Requester must read the following and sign below:

I certify that the hazardous material I am presenting for shipment is described truthfully to the best of my ability. All information provided is complete and accurate to the best of my knowledge. I accept full responsibility for the description of the hazardous material to be shipped.

Requester's Signature:

Print Name: Date:

Request to Ship Hazardous Materials Document approved by:

Signature: Print Name:

Date Reviewed: Date Approved: