Ask RCRA about....

Considerations for International Shipping

Rose Ndegwa - Export Control Office Dr. Raj Guddneppanavar – Office of Technology Transfer Dr. Kalpana Rengarajan and Robin Ruthenborg – Environmental Health and Safety Office



- The U.S. federal government's laws and regulations on export controls apply to export or transfer of certain commodities and technologies.
- Obligates the shipper to specific compliance requirements.





#1 Export License

- International shipment may require an **export license** i.e., written authorization from federal agency
- Whether a license is required depends on
 - What is being shipped
 - Where it is being shipped to, i.e., destination
 - End User who is receiving the shipment? Are they on any restricted list?
 - End Use: what recipient will do with it
- Applies to commodities as well as technical information/data, software





#2 Filing of Electronic Export Information (EEI)

- A requirement under Foreign Trade Regulations
- Not an approval process but must be filed prior to export.
- Required for
 - Items valued at \$2500+
 - Items requiring an export license, regardless of \$ value
 - Most <u>permanent</u> shipments of China, Venezuela and Russia





#3 Comprehensively Sanctioned Countries

- Any shipment (temporary or permanent) to these countries will require a license (or other authorization)
 - Cuba
 - Iran
 - Syria
 - North Korea
 - Ukraine regions of Crimea, Donetsk and Luhansk





Important Note

- Method of Shipping: Compliance requirements apply regardless of how the item is shipped. Items in carry-on or checked baggage items are NOT exempted.
- Export Control Office evaluates your shipment to determine compliance obligations, requests licenses and makes EEI filings on behalf of person making the shipment.
- You have questions? We are here to help!
 - Email us at exportcontrol@emory.edu
 - See additional information on our website www.or.emory.edu/export-control







Outgoing Material Transfer Agreements

Rajsekhar Guddneppanavar, PhD Assistant Director, Licensing Office of Technology Transfer Emory University, Atlanta, Georgia

For MTA requests or more information about MTAs, contact the general inbox at **ottmta@emory.edu**



Shipping of research materials will likely require a Material Transfer Agreement (MTA)

- MTA is a legal agreement that governs the transfer of research materials from one entity to another.
- Importance
 - Limiting Liability of the Principal Investigator and Emory
 - Protecting Emory Intellectual Property
 - Prevent Emory from losing control over the material and its research use



Outgoing MTAs

When is an MTA needed?

MTAs are required for the transfer of tangible research materials (mice, plasmids, human tissue specimens, cell lines, reagents, compounds, etc.) out of Emory in connection with basic research.

- <u>An MTA is not needed to:</u>
 - Transfer tangible research materials out of Emory in connection with a fee-for-service work. In this case, a service agreement would be required rather than an MTA.
 - Transfer tangible research materials out of Emory in connection with basic research collaborations, sponsored research, consortiums, and subawards, <u>if</u> such agreements already contain appropriate material transfer language.
 - Transfer tangible research materials out of Emory in connection with a clinical trial. In this instance, a clinical trial agreement would be required rather than an MTA.



Outgoing MTAs

Special considerations

Transfer of human subject derived materials

Sharing materials derived from human subjects (blood samples, tissues, saliva, cell lines, etc.) requires extra consideration, as Emory must ensure that the rights of the subjects from whom the materials were obtained have been safeguarded, and, if required, have protocol(s) reviewed and approved by the Institutional Review Board (IRB).

Transfer of materials created using other materials

If a researcher wishes to share materials that have been created using other materials obtained from third parties, Emory is likely to have obligations to the provider of those component materials that need to be met before further distribution can be approved.

• What else is needed to send materials after an MTA is completed?

Once an MTA is completed, Emory researcher may transfer the materials, but still needs to make sure that s/he complies with any other shipping requirements, such as animal transport polices, regulations regarding transfer of hazardous and toxic materials, and export control laws, where applicable

Shipping and Transport of Biological Materials and Refrigerants

Environmental Health & Safety Office (EHSO) 404-727-5922 ehso@emory.edu | etraini@emory.edu

Presenter: Dr. Kalpana Rengarajan Research Safety, Director | Institutional Biosafety Officer



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Who requires training and how often?

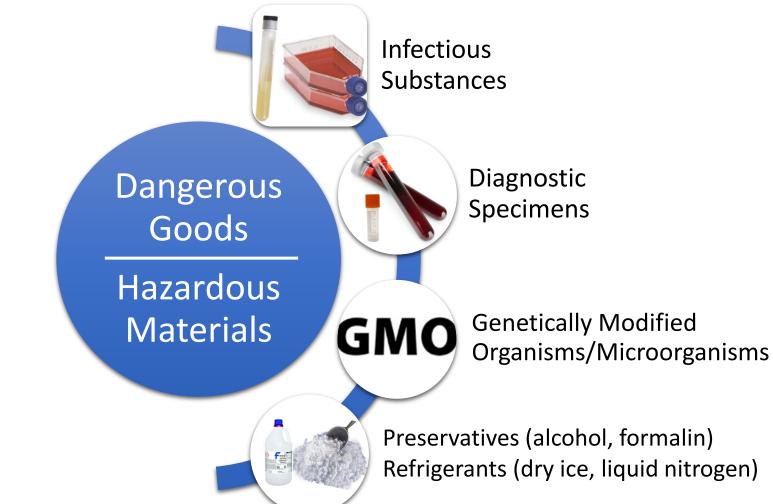
Anyone who prepares packages or documents for the shipment of biological materials and refrigerants

- Determining if a shipment should be classified a dangerous good/hazardous
- Selecting packaging (shipping box systems)
- Marking and/or labeling a package

 Preparing and/or reviewing shipping papers, including generating labels from FedEx/UPS systems Emory University requires shipping training to be completed **every 2 years**

- International Air Transportation Association (IATA) Dangerous Good Regulations > every 2 years
- Department of Transportation (DOT) Title 49 Code of Federal Regulations (49 CFR) > every 3 years

Examples of Biological Agents and other Dangerous Goods often included in Biological Shipments

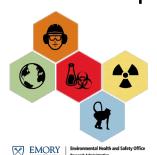




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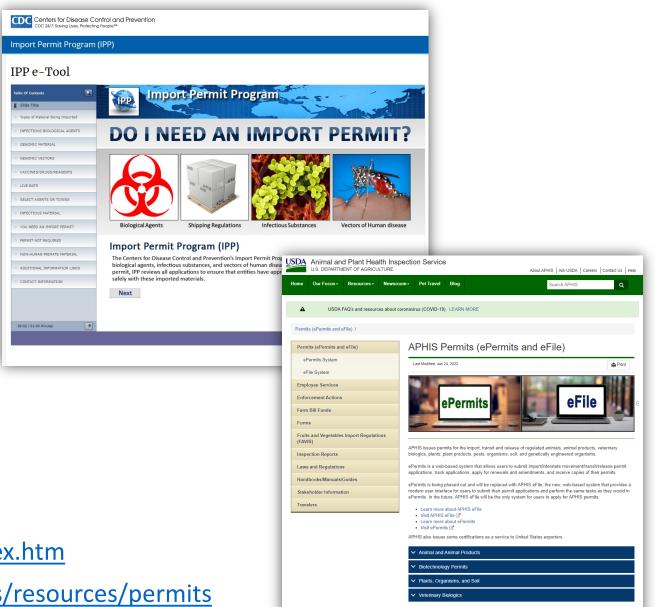
Other Shipping Documentation

- Import and/or Export permits may be required for international shipments.
- Permits may also be required for interstate transport.
- CDC and USDA have resources on their websites that assist with determining if a permit is required.



https://www.cdc.gov/cpr/ipp/index.htm

https://www.aphis.usda.gov/aphis/resources/permits



What happens if I don't complete training or acquire permits?

- The Federal Aviation Administration (FAA) can impose significant fines.
 - Institution
 - Individual shipping personnel
 - Supervisor

<u>Example</u>: \$54,000 fine for shipment of 6 bottles of flammable liquid not accompanied by a Shippers' Declaration and was not properly classified, packaged, marked, or labeled. The FAA discovered the institution did not ensure that each of its employees received required training for hazardous materials.



Where do I take the online Biological Materials Shipping Training?

EHSO has partnered with CITI Program to offer Emory's research community free access to online Shipping and Transport of Biological Materials and Refrigerants training.

 For instructions on how to login, access, and complete the online CITI shipping training:

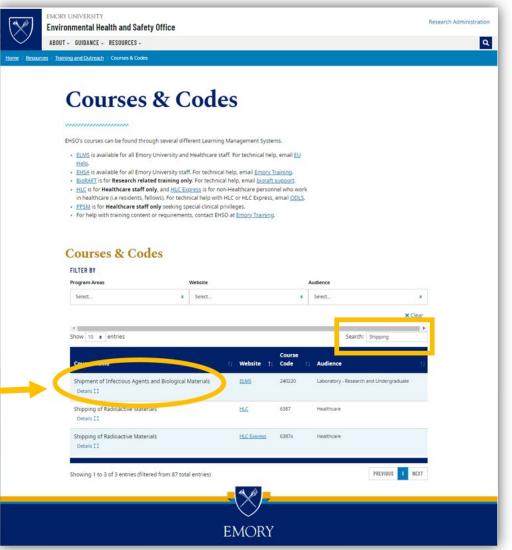
https://www.ehso.emory.edu/resources/ training/courses.html

> click Details [] '

EMORY

ntal Health and Safety Offic

 Questions: email <u>etraini@emory.edu</u> or <u>ehso@emory.edu</u>



Questions for the Panel

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