GENERAL STATEMENT OF PURPOSE

To define the training requirements for shipping infectious substances and diagnostic specimens, radioactive and other hazardous materials.

POLICY

Employees responsible for packing and shipping of infectious substances, diagnostic specimens, genetically modified organisms, biological products, dry ice, radioactive and other hazardous materials must comply with required training and ensure current certification is maintained. Only those who have been trained and are certified can pack or ship these materials.

SCOPE

This policy applies to all members of the workforce of the North Shore-Long Island Jewish Health System who are engaged in the shipment of infectious substances, diagnostic specimens, genetically modified organisms, biological products, dry ice, radioactive and other hazardous materials.

DEFINITIONS

United States Department of Transportation (DOT) – The DOT is a federal agency that oversees interstate travel throughout the United States to ensure a fast, safe, efficient, accessible and convenient transportation system that meets national interests and enhances the quality of life of the American people, today and into the future.

Federal Aviation Administration (FAA) – The FAA is an agency of the DOT responsible for civil aviation. The FAA has the authority to regulate and oversee all aspects of civil aviation in the United States. Its mission is to provide the safest, most efficient aerospace system in the world.
International Air Transport Association (IATA) – The IATA is an international industry trade group of airlines. Its mission is to represent, lead and serve the airline industry. This agency regulates the shipping of dangerous goods.

International Civil Aviation Organization (ICAO) – The ICAO is an agency of the United Nations that codifies the principles and techniques of international air navigation and fosters the planning and development of international air transport to ensure safe and orderly growth.

Infectious Substances – The most commonly shipped hazardous materials within the Health System are covered under Hazard Class 6, Division 6.2 Infectious Substances. Infectious substances are those that contain known or suspected pathogens, such as microorganisms (including bacteria, viruses, parasites, fungi) or other agents which can cause disease in humans or animals. Infectious substances are classified according to the degree of hazard into two categories; A and B. Training is required for anyone shipping any of these materials.

- **Category A Infectious Substances**  
  A Category A infectious substance is one that is in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal diseases to humans or animals. These are subject to the strictest shipping requirements (special paperwork, labels, containers), whether in cultures or in human or animal specimens.

- **Category B Infectious Substances**  
  All other infectious substances are classified as Category B infectious substances. These are still subject to shipping regulations but with lesser requirements in terms of shipping papers and quality of containers. Included in this section are human and animal diagnostic specimens (blood, blood components, excreta, secreta, tissues, etc.). This includes specimens from healthy patients.

- **Genetically Modified Organisms (GMOs)**  
  Genetically modified organisms and microorganisms may meet the definition of infectious substances. Those GMOs which do not meet the definition of infectious substances, but which are capable of altering animals or plants or microbiological substances in a way which is not normally the result of natural reproduction are considered Class 9 Miscellaneous Hazards, for which shipping training is also required.

Preservatives – Hazardous or flammable chemicals used to preserve specimens are considered hazardous materials. Dry ice, a common preservative, is a Class 9 Miscellaneous Hazard. Shipping training is required.

Laboratory Response Network (LRN) – The LRN is a consortium of medical and other institutions intended to respond to biological and chemical terrorism, emerging infectious diseases, and other public health emergencies. Some hospitals within the Health System participate in this program.
REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

Title 49 CFR (Code of Federal Regulations) 172.700-704, IATA Section 1.5

Federal regulations require hazardous materials training for every “Hazardous Materials Employee.” The DOT requires every “Hazardous Materials Employer” to provide all the necessary information to hazardous materials employees so they can perform their individual job functions in a safe and knowledgeable manner.

Hazardous Materials shipped by ground or air must comply with the most current Hazardous Material Regulation as documented in 49 CFR and in the most current version of regulations promulgated by ICAO and the IATA. The IATA and DOT require individuals shipping hazardous materials (such as infectious substances and diagnostic specimens) to be properly trained in conformance with 49 CFR. The IATA and DOT also require that hazardous materials be properly classed, described, packaged, marked and labeled, and be in condition for shipment as required or authorized by applicable regulations of 49 CFR. Federal Regulations associated with the shipping of hazardous materials are enforced by the FAA through routine inspections. Inspections focus on four main areas: recordkeeping, training, labeling and shipping containers.

Compliance with Federal Regulations requires shipping certification via approved training courses for all staff involved in the shipping of hazardous materials including, but not limited to infectious material, biological substances, human and animal specimens, dry ice, etc. Failure to comply with these regulations will result in regulatory enforcement actions.

Title 49 CFR 173.199

Federal regulations that define the handling of Category B infectious substances, diagnostic specimens and used health care products in order to prevent breaks, punctures or leaks during transport.

PROCEDURE

For Health System employees to be compliant with this policy they must complete an appropriate training program.

As per your job responsibilities:

- If you will be placing (or preparing for placement) diagnostic specimens in a laboratory drop box, you need to be knowledgeable about Category B infectious substance handling procedures listed in 49 CFR 173.199. You must understand classification, and follow all packing and marking instructions. Formal hazardous materials training and certification is not required.

- If you will be packing and/or shipping diagnostic samples and infectious substances, you must be trained and certified with a program that provides basic information necessary to safely and legally classify, package, and ship medical specimens and to comply with IATA and D.O.T. training requirements, such as the Mayo Clinic Lab training program (see page 4).
• If you will be packing and/or shipping diagnostic specimens and infectious substances to the New York State Department of Health’s Wadsworth Center or another designated site as part of the Laboratory Response Network, you must be trained and certified. A more comprehensive program, such as the SAF-T-PAK training program (see page 4) is preferable.

• If you are a mail room or receiving employee, who has been designated by your department head to be knowledgeable about shipping regulations affecting your facilities scope of services, you should be trained with the most appropriate program. You should start with the Mayo Clinic Lab training program (see page 4). Certification is not required.

• Only select employees are permitted to handle radioactive materials. If you will be packing and/or shipping radioactive materials, you must first contact your facility Radiation Safety Officer for complete details on training/certification requirements.

• Only select employees are permitted to handle other hazardous materials, such as corrosives and flammables. If you will be packing and/or shipping other hazardous materials, you must first contact your facility Safety Officer for complete details on training/certification requirements.

Training options that cover materials for Division 6.2, Infectious Substances, and Class 9, Miscellaneous Hazards, including classification and identification, packaging requirements, marking, labeling, documentation, and emergency actions are the Mayo Clinic’s Dangerous Goods Training and the SAF-T-PAK Training. Information about these programs follows. Regulations require staff to receive training every two years.

The Mayo Clinic Laboratories facilitates the approved Dangerous Goods Training.

➢ Visit the Mayo Medical Laboratories website at http://www.mayomedicallaboratories.com/education/online/dangerousgoods/index.html and select a training option. This course is available at no cost.

The approved SAF-T-PAK Internet Training.

➢ Contact SAF-T-PAK by telephone at 1-800-814-7484 for information about this training program. Costs will be based on the number of training seats needed. Departments will be responsible for costs incurred.

The employee is required to pass a quiz based on the federal regulations and obtain a record of training for the handling/offering for transport of dangerous goods. A copy of the certification must be maintained by the employee, be available for inspection, and be given to others as directed by the employee’s Department Director/Head. It is the responsibility of the employee to maintain appropriate certification and renew certification as warranted. Department Directors/Heads must ensure that employees in his or her department who pack and ship are properly trained. Each Department Director/Head should maintain a current master list with the names of all employees qualified to pack and ship.
AUDITING AND MONITORING

Internal Audit, Research Compliance, and other various department personnel responsible for quality and safety may conduct periodic routine and for cause monitoring. It is the responsibility of all employees to conduct themselves in compliance with this policy. Employees may report incidents of non-compliance via the Corporate Compliance Help Line at telephone number 1-800-894-3226 or by web-based reporting at www.northshore-lij.ethicspoint.com.

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