



**Nova Southeastern University  
Standard Operating Procedure for GCP**

<b><u>Title: Training Requirements for Packaging and Shipping of Specimens</u></b>		<b>Version # 1</b>
<b>SOP Number: OCR-LAB-003</b>	<b>Effective Date: August 2013</b>	<b>Page 1 of 2</b>

**PURPOSE:** The safety of our employees, the general public and integrity of research specimens resulting from accidents or incidents involving the packaging and transport of specimens can be better assured through proper training.

**POLICIES:**

1. Employees packaging specimens shall be trained in the appropriate classification, identification, packing, marking, labeling, documenting, and arranging for acceptance by a courier for transportation.
  - 1.1. Employees who package substances classified by the Department of Transportation as Category B INFECTIOUS SUBSTANCES (Division 6.2) for shipment will receive training consistent with the applicable regulations (49 CFR 173.199 and 49 CFR173.217- a.k.a. "Hazardous Materials Regulations" ) and tested to these standards.
  - 1.2. If Center/College's employee does not already have certification (a.k.a. "DOT/IATA Certification") a web-based self-training module should be completed before beginning any research activities. Such employees (as the Department of Transportation identified as "HazMat Employees") are limited in their scope of hazardous materials to Class 6.2 INFECTIOUS SUBSTANCES, AFFECTING HUMANS and Class 9 DRY ICE unless receiving function specific training for other classes of hazardous materials.
2. It is the Center/College's responsibility to assure that the employees are adequately trained.

**Procedure for Diagnostic Specimens Training**

1. All research employees or other employees that may assist in this function of the research process shall access OCR website and complete the most

current module entitled "Packaging Biological Specimens, Category B" and post test prior to undertaking duties.

2. All research employees or other employees that may assist in this function of the research process shall repeat recurring 3-year training.
3. As modules are updated, employees shall complete the updated modules.
4. Certification.
  - 4.1. After the employee reviews the training materials, they will complete the Post-Test;
  - 4.2. The Post-Test is submitted to the OCR, scored and the results are kept at OCR.

Once the employee scores 100% on the post test questions, the OCR will maintain a copy of the post test in the regulatory file.

### **Procedures for Dry Ice Training/Packing**

1. Establish if Dry Ice Certification is needed (usually it is not):
  - 1.1. Dry Ice certification is not required when
    - 1.1.1. packaged in quantities not exceeding 2.3 kg (5.07 pounds) per package
    - 1.1.2. packed in packaging designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging
    - 1.1.3. used as a refrigerant for the contents of the package.

The package must be marked with the name of the contents being cooled (e.g. Diagnostic Specimens), the net weight of the dry ice or an indication that the net weight is 2.3 kg (5.07 pounds) or less, and also marked "Carbon Dioxide, Solid" or "Dry Ice"