# **Regulated Materials Procurement Procedure**

# **Acquisition of Regulated Materials**

**A.** All items on the following lists are restricted and shall not be purchased by any department without approval of the Office of Environmental Health & Safety (OEHS). Regulatory guidelines rapidly change; therefore, the most recent regulatory information shall take precedence over UAH provided information.

#### 1) Particularly Hazardous Substances

These items are chosen because they are designated by the Occupational Safety and Health Administration as:

- Select Carcinogens
- Reproductive Toxins
- Acutely Toxic

# 2) Toxic Release Inventory (TRI)

These items are chosen because they cause or have:

- Cancer or other chronic human health effects
- Significant adverse acute human health effects
- Significant adverse environmental effects

#### Controlled Substances List I and List II

Congress passed the Chemical Diversion and Trafficking Act (CDTA) in 1988. Subsequent amendments placed 41 chemicals under control. These laws provide a system of regulatory controls and criminal sanctions to address both domestic and international diversion of important chemicals without interrupting access to chemicals destined for legitimate commerce. The CDTA created two categories for the controlled chemicals.

#### 4) Radioactive Materials

The UAH Radiation Safety Officer must approve the purchase or disposal of radioactive materials.

## 5) **DEA Controlled Substances**

Due to their potential for misuse and abuse, items listed by the Drug Enforcement Administration (DEA) as Schedule I to V drugs are subject to special procurement, storage, use, and disposal requirements. Additional federal and state licensing is required prior to procurement of DEA Controlled Substances.

#### 6) Biohazardous Materials

The categories below represent the areas of primary concern with respect to biosafety.

1. Infectious agents requiring handling conditions above Biosafety Level-1. (Biosafety Level determinations are based on the recommendations outlined by the CDC-NIH publication <u>Biosafety in</u>

## Microbiological and Biomedical Laboratories.)

#### 2. Recombinant DNA.

#### **Definitions For Clarification**

- Recombinant DNA (rDNA) molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
- Nucleic acids that are not and cannot be replicated inside organisms, cells, or viruses are not considered rDNA. Commonly encountered examples of synthetic DNA not considered to be rDNA include Polymerase Chain Reaction (PCR) products, synthetic oligonucleotides/primers, and complementary DNA (cDNA) obtained by reverse transcription of RNA.
- 3. Human or non-human primate blood and blood products, human or non-human primate body fluids, and/or human or non-human primate tissue.
- 4. Toxins produced by living organisms (>1 mg of pure toxin, or solutions with concentrations of >1 mg/ml pure toxin). This provision excludes toxins covered by the Select Agent regulations (see #5).
- 5. HHS and USDA Select Agents and Toxins, as defined in Federal Regulations 7CFR331, 9CFR121, and 42CRF73, Additional Requirements for Facilities Transferring or Receiving Select Agents, Public Law 107-188, Public Health Security and Bioterrorism Response Act. These regulations also apply to nucleic acids that can produce infectious forms of any select agent virus, and recombinant nucleic acids that encode the functional forms of any select agent toxin.
- 6. USDA Restricted Animal Pathogens, as determined by the United States Department of Agriculture (USDA).
- **B.** Departments utilizing regulated materials shall develop internal policies and procedures for the acquisition and use of these products. The policies and procedures will be recommended by the Department Head and approved by the Dean of the College and the OEHS. The policies will be attached to this policy and reviewed on an annual basis.
- **C.** The individual initiating the purchase has the following responsibilities:
  - 1. To have current knowledge about the hazards and the safe handling of regulated materials.
  - 2. To train employees about the hazards and safe handling guidelines.
  - 3. To notify the Department Head about regulated materials.
  - 4. To notify the appropriate stock room manager about regulated materials when applicable.
  - 5. To ensure their chemical inventories are updated when hazardous materials are added to a laboratory or stock room.
  - 6. To notify the Procurement Department that the item is on one or more of the regulated materials list(s) by using the appropriate purchasing account code.
  - 7. To notify and arrange for immediate delivery of the substance once received at Central Receiving.

- **D.** The department using the material shall comply with the requirements of this policy and all UAH policies and procedures for handling regulated material.
- **E.** The OEHS will coordinate with the Director of Procurement to ensure the following:
  - 1. Procurement will process purchase requisitions for regulated materials.
  - 2. The OEHS must approve purchase orders for Regulated Materials.
    - a. The OEHS will approve purchasing documents twice daily.

## **F.** Director of Procurement

All purchase orders for restricted items will carry a stamped or typed imprint which states:

"You are requested to furnish the Safety Data Sheets (SDS) on the items requested on this Purchase Order. The SDS should be included with the shipment with the packing slip and also be sent to:

UAH

301 Sparkman Drive (campus address of individual requesting purchase/using the material) Huntsville, AL 35899

ATTN: Name of person requesting purchase/using the material"

- 1. Copies of all purchase orders for hazardous materials will be sent to the person requesting purchase/using the material and remain on file pending receipt of the requested SDS. SDSs may also be available at https://www.uah.edu/oehs
- 2. Procurement and Central Receiving will send all SDS received by their offices to the person requesting/using the hazardous material.
- 3. The person requesting/using the material will inspect all SDS for purchased substances to assure that the SDS is dated, complete, "not obviously unacceptable", and contain the information specified in the Hazardous Communication Standard. The University will rely "in good faith" on the hazard determination performed by the manufacturer when the SDS is received. Should the SDS prove to be deficient, the University shall inform the manufacturer of the deficiency and attempt to secure an updated SDS which meets the requirements of the Hazardous Communication Standard. In the interim, the University will rely on the information as provided by the manufacturer for substances already in stock.
- 4. Should a manufacturer prove unable or unwilling to provide the University with an adequate SDS, the University will cease using the substance as supplied by the manufacturer and dispose of existing inventories in accordance with local, state, and federal regulations.

## **Central Receiving and Warehousing of Regulated Material**

# A. Receiving inspections

- 1. It is the responsibility of Central Receiving & Shipping to perform the following when a shipment is received **and is possibly damaged**:
  - a. Check the packing slip for SDS before opening package.
  - b. Follow safety procedures listed on the SDS for personal protection before opening package.

- c. If the material is damaged, arrange a joint inspection or examination of the contents by the Carriers' representative and a Central Receiving & Shipping representative as soon as possible. Notify the UAH OEHS of the damaged shipment.
- d. If the carrier has left, place the damaged regulated material in a secure location that will not allow the spill to release into the environment and immediately call the OEHS at 6053 or the UAHPD at 6596. If the container packaging and or markings indicate a toxic inhalation hazard evacuate the building immediately.
- 2. It is the responsibility of the department receiving packages to perform the following when a shipment is received with potential concealed damage:
  - a. Check the invoice for a SDS before opening package. If the SDS is not on the packing list, contact the person requesting the purchase of the material/user of the material. The user must ensure a copy of the SDS is on sight. Do not open until a SDS has been reviewed and appropriate safety measures are taken.
  - b. Packages will be opened as soon as possible and inspected for concealed damage of materials.
  - c. If damage is discovered, procedures for personal safety will be followed as listed on the SDS.
  - d. Arrangements must be made to have the product stored in an appropriate containment area.
  - e. UAHPD and Central Receiving & Shipping must be notified immediately.
  - f. As proof of receipt of goods, all packaging material and cartons in which the goods were received must be retained, unless immediate disposal is necessary, to avoid a threat to health and safety.
- 3. Central Receiving & Shipping will forward to the Procurement Department all related documents to be assembled and transmitted with the claim to the Vendor, or the Carrier, responsible for the loss incurred from the damage. Report damages to the Carrier within 15 days of delivery of the materials.
- 4. Labeling for regulated materials
  - a. Delivery will be refused for all unlabeled containers, containers bearing illegible labels, and inadequately labeled containers.
  - All portable containers (over 60 U.S. gallons and not intended for fixed installation) used on the University will be labeled with the contents' identity and appropriate hazard warnings.
  - c. All stationary tanks will be labeled with the identity of the contents and appropriate hazard warnings.

## **On-campus Transportation or Delivery of Regulated Materials**

**A.** Warehouse personnel will deliver regulated materials to user locations unless specified otherwise by regulatory agencies.

- 1. No damaged hazardous materials including hazardous waste containers will be moved on campus.
- **B.** Immediately report any on-route damage to the UAHPD; evacuate and secure the vehicle.
- C. If damage occurs outdoors or in a building, immediately notify the UAHPD

# **Special Situations/Exceptions**

The OEHS will review written requests concerning variances, modifications and requests for exceptions to the policies. The appropriate University committee will address any appeals to the final decision.

Direct any questions regarding the interpretation of this procedure to the OEHS.