

**University of Cincinnati  
Animal Care and Use Program**

**Use of Expired Materials, Non-Pharmaceutical Grade Substances and  
Labelling Requirements**

**Definitions**

1. **Medical materials** - clinical supplies used for research purposes that may have a vendor- imprinted expiration date (e.g. suture, surgical packs, devices).
2. **Acute/terminal procedure** - a procedure where an animal receives and is euthanized without recovery from anesthesia.
3. **Survival procedure** - a procedure where an animal receives and is allowed to recover from anesthesia.
4. **Substance** - drug, biologic, chemical, or reagent that can be administered to an animal.
5. **Pharmaceutical grade substance** - a drug, biologic, or reagent that is approved by the Food and Drug Administration (FDA) or for which a chemical purity standard has been established by the United States Pharmacopeia-National Formulary (USP-NF) or British Pharmacopeia (BP).
  - a. [FDA Orange Book](#) - approved human drugs
  - b. [FDA Green Book](#) - approved veterinary drugs

**Expired Materials**

The use of expired pharmaceuticals, biologics, and supplies (e.g., drugs, fluids, sutures) is inconsistent with adequate veterinary care.

1. Expired substances/compounds, including but not limited to: analgesics, sedatives, anesthetics and euthanasia solution must **NOT** be used in live animals for any reason. They must be clearly labeled “NOT FOR USE IN ANIMALS” or “EXPIRED” and stored in an area physically separate from those *used in animals*.
2. Expired medical materials may be used in acute terminal procedures and must be clearly labeled “TERMINAL PROCEDURES ONLY”.

**Non-Pharmaceutical Grade Substances** <sup>1 2 3</sup>

If available, pharmaceutical grade substances must be used for all vertebrate species. In certain circumstances, use of non-pharmaceutical grade substances is sometimes necessary to meet research objectives. IACUC approval is required **prior** to use of a non-pharmaceutical grade substance. Non-pharmaceutical grade substances may be approved by the IACUC if there is:

1. Appropriate scientific justification. Cost is not considered adequate justification for using a non-pharmaceutical-grade substance.
2. The pharmaceutical-grade compound is not available in the appropriate concentration or formulation, or the appropriate vehicle control is unavailable.
3. The compound is required to generate data that are part of an ongoing study or that are comparable to previous work.

**Substance Preparation and Labelling Requirements**

Substance stock, mixture, and dilution solutions should be prepared, labeled, administered, and stored appropriately to ensure consistent sterility, stability, and quality.

When preparing, mixing, or diluting substances in solution for **injection**:

1. Store solutions in a re-sealable sterile secondary container. **Sterile injection vials** are preferred for ease of drawing the solution into a syringe without exposing the solution to outside contaminants.
2. Sterile diluents or vehicles should be pharmaceutical grade where available.
3. Solutions should be between pH 4.5 and 8.0.
4. Solutions must be checked for contamination and precipitation (e.g. discoloration, unusual growth) prior to use.
5. Prepared solutions should be passed through a sterile **syringe filter** (0.22 micron or finer) into a sterile container during preparation and/or at the time of use.
6. Storage: Substances must be stored based on compound-specific stability, solubility, and compatibility (e.g. light sensitivity, temperature degradation).

When preparing, mixing, or diluting substances for **oral, rectal, or topical administration**:

1. Substances administered should minimally be food-grade (level of purity)<sup>3</sup>.
2. Prepared solutions/food mixtures are not required to be kept sterile.

National Research Council, FDA, and AAALAC International recommend that all secondary substance containers must be clearly and completely labeled.

**Labels should include:**

1. Name of the substance(s) exactly as written on primary container
2. Concentration of the primary substance(s) (e.g. mg/mL)
3. Date of expiration (preparation date is not an acceptable alternative)
4. Label the container "in vitro" or "in vivo"
  - a) *In vivo* includes all oral, injectable, inhalant, or topical substances used with live animals.

### **References**

1. [OLAW Frequently Asked Questions](#)
2. *Guide for the Care and Use of Laboratory Animals* (8th ed., Chapter 2, p. 31)
3. OLAW Online Seminar: Use of Non-Pharmaceutical -Grade Chemicals and Other Substances in Research with Animals, March 1, 2012.  
[https://grants.nih.gov/grants/olaw/120301\\_seminar\\_transcript.pdf](https://grants.nih.gov/grants/olaw/120301_seminar_transcript.pdf)