FSU ACUC
Policy on Expired Materials in Animal Housing and Procedural Areas

Federal policies, regulations and rules prohibit the use of expired material in the course of animal research with few exceptions.

> ***PHS Policy per OLAW FAQ:*** *The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. Euthanasia, anesthesia and analgesia agents should not be used beyond their expiration date, even if a procedure is terminal. Other expired materials should not be used unless the manufacturer verifies efficacy beyond the expiration date, or the investigator is able to document to the satisfaction of the IACUC that such use would not negatively impact animal welfare or compromise the validity of the study. The veterinarian and IACUC must maintain control over the use of expired medical materials in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.*
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> ***USDA:*** *Policy #3 - The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and is not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. The facility should either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. … For acute terminal procedures, where an animal is put under anesthesia, the research is carried out (surgery or testing of a compound) and the animal is euthanized without ever waking up, medical materials may be used beyond their "to be used by" date if such materials use does not adversely affect the animal's wellbeing or compromise the validity of the scientific study. Anesthesia, analgesia, emergency drugs and euthanasia drugs that are within their expiration dates are required for all such procedures. Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials. The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. APHIS has determined that these responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.*

In accordance with the above federal policies, the FSU ACUC adopts the following policy:

- Medical material refers to any drug or pharmaceutical agent, reagent, solution, biological product or disposable medical device or supply (e.g suture, gloves, catheters) used in the course of animal research.

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- Medical materials must be used before their expiration date. Prior to or upon expiration they must be promptly segregated from in-date items and appropriately disposed of in a timely fashion (or may be utilized in other, non-animal, work).
- Expired anesthetic, analgesic and euthanasia agents may never be used, even for terminal procedures.
- Expired medical materials (other than anesthesia, analgesia or euthanasia agents) may be used for acute terminal procedures provided that their use does not adversely affect the animal's well-being or compromise the validity of the scientific study. However the use of any expired solution, fluid, non-pharmaceutical or pharmaceutical agent or implant must receive prior approval by the ACUC. Expired medical materials must be clearly marked 'Expired, terminal use only' and physically separated from non-expired materials to prevent accidental use. The storage location must also be clearly labeled "Expired Materials".
- The ACUC strongly recommends that each laboratory establish an inventory procedure to identify and separate or dispose of expired drugs, fluids, dilutions, lab preparations, mixtures, medical supplies, materials, and devices. Inventories should be performed on a routine basis (preferably at least once/month). Identification of expired medical devices during inspections will be considered a deficiency and may result in mandatory inventory reporting to the ACUC.
- Disposal services for expired drugs and/or controlled substances are available at no cost to the investigator by calling EH&S Biological Waste at 644-5374 or EH&S Chemical Waste at 644-7682.

Identification of Expiration Dates

At this time there is no industry standard format for expiration dates. Items with expiration dates may be labeled as Exp, expiration date, expires or best used by followed by a date. Variations in the date include: mm/dd/yyyy, yyyy/mm, mm/yy/dd, mm/yyyy, mm/yy or (month)/yyyy. Expiration dates may also take the form of an hour glass symbol with one of the above date formats (see example). If the expiration date has only a month and a year listed (e.g. Nov 2011), then per the U.S. Pharmacopeia standards the drug or item expires on the last day of the month.

Some supplies or devices will only have a date of manufacture. In general, those items will be considered expired three years from the date of manufacture unless otherwise supported by information from the manufacturer or published data. To the right is an image of the symbol for the date of manufacture. This symbol is accompanied by a date.

Note: Bulk chemicals and chemical reagents. Check the manufacturer for quality assurance documentation or recommendations. Storage and handling should follow manufacturer recommendations (or will default to industry standards). If the bottle is not labeled with an

expiration date or a retest date (in other words, the shelf life has not been determined), then it will be treated as per the industry's standard. Industry standard laboratory practices is that products with no expiration date or retest date must be used or discarded within 5 years of opening. Label all containers with the date it was first opened or received. Investigators have the option to demonstrate retained potency by stability testing or data from current experimental use equal to that of original receipt.

Role of the Investigator

- Investigators are responsible for ensuring that all drugs and medical materials used in their laboratories are within the expiration or retest date. All chemicals, drugs and medical materials used in animals must be labeled with an expiration date, a date of preparation or date of receipt or opening.
- Investigators are responsible for ensuring that routine inspection for identification of expired medical materials is performed in their animal housing, procedural areas, storage areas and refrigerators.
- All expired medical materials for use in acute terminal procedures must be stored in a physically separate area from non-expired materials and labeled "Expired Materials: for acute non-survival use only" or equivalent. Use of expired materials in terminal procedures must be approved in advance by the ACUC.
- It is strongly recommended that all expired medical materials for *in vitro* use be stored in a physically separate area from both non-expired materials and expired materials for acute non-survival use, and labeled "Expired Materials: for in vitro use only" or equivalent.
- All chemicals, drugs and medical materials should be stored according to manufacturer recommendations as well as any applicable state or federal requirements.

Role of the Veterinary Staff and ACUC

The Attending Veterinarian and the Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. On semiannual inspections, the ACUC inspection team will determine if expired materials are being kept in an appropriate manner. Expired material deemed not to be stored or labeled appropriately will be considered a deficiency and may be confiscated and discarded.

How Investigator Labs Can Make Inventory Control Easier:

The following tips are suggested to help laboratories implement this policy:

1. Store drugs, chemicals used in animals and materials with expiration dates in a limited number of locations. For example, a main drug storage cabinet for in the lab, a drug safe for controlled substances, dedicated cabinets or shelves to store surgical materials and

gloves and only very limited drugs or materials in one specific location in an animal housing or procedure location.

2. Consider assigning the inventory responsibilities to one specific individual, with another individual assigned as backup.
3. Place additional, eye-catching labels or signage on the containers with the dispose by date to avoid having to handle each item individually in order to locate the date each month.
4. Establish an inventory system which minimizes the amount of drug or medical supplies on hand. The majority of items can be ordered with a very quick turnaround time from ordering to delivery.
5. Perform monthly checks of your inventory and discard or segregate all expired drugs or medical materials.
6. If also concerned with budget, contact your suppliers to see if they will accept the return of some expired drugs or medical supplies for credit.
7. After segregating expired drugs and medical materials in a clearly labeled container or location, contact FSU EH&S, the supplier or manufacturer for disposal or return to the supplier or manufacturer.

Additional Items of Note:

- **Gloves:** The FDA considers medical gloves (surgical and exam) as class I reserved devices that are subject to general controls (section 513(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act (Act); 21 U.S.C. 360c(a)(1)(A)), While labeling for expiration dates by manufacturers is voluntary, expiration dates are based upon actual stability tests and may allow gloves to be considered usable up to 5 years from date of manufacture. If no expiration date is listed then gloves are considered stable for up to 3 years from date of manufacture. If no expiration date or date of manufacture is listed, then boxes should be labeled with a date of receipt. Note that pre-packaged sterile surgeon's and patient examination gloves have an expiration date based on sterility that is different from the expiration date based upon physical and mechanical integrity testing.
- **Multi-dose containers or vials of liquid formulations**:
  - United States Pharmacopeia (USP) General Chapter 797 recommends the following for multi-dose vials of sterile commercial pharmaceuticals containing preservative:
    - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
    - If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.
  - Preservative free containers or vials of a liquid formulation are typically considered single use, to be administered and discarded within 24 hours of opening/puncture of septum. Use of the product may be extended if aliquoted into sterile containers and stored appropriately. The ACUC may approve a longer beyond use time (up to 7 days) if the investigator provides justification in their Appendix D.
  - Never leave a needle in the septum of a medication vial for multiple medication draws. This provides a direct route for microorganisms to enter the vial and contaminate the fluid

- **Sterilized Supplies:**
  - The FSU ACUC adopts an event related shelf life practice. This means that the packaged medical material or device should remain sterile until some event causes the item to become contaminated. This applies only to those items that have been appropriately packaged (e.g. wrapped in muslin or paper, peel bags or sleeves, etc.) and sterilized. (HICPAC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)
  - To qualify, sterilized supplies must be stored in a clean, dry, insect free, enclosed cabinet, drawer or container. Storage may not occur below a sink.
  - The maximum shelf life under these conditions will be one year from date of sterilization.
  - A sterilized supply item is considered contaminated when it becomes wet, is torn, the seal is broken, is dropped on the floor, is damaged in any way, or past its date of expiration. When such events occur, the contents should be removed, repackaged, and re-sterilized. Contaminated items may not be used for either survival or non-survival procedures without first being re-sterilized.

References:

Sigma-Aldrich Product Dating Information Statement (February 2016). Downloaded September 23, 2016. http://www.sigmaaldrich.com/customer-service/quality-systems/product-dating-information-statement.html

United States Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding – Sterile Preparations. Second Edition, June 1, 2008.

Centers for Disease Control. One and Only Campaign. Available from: http://oneandonlycampaign.org/safe_injection_practices. Accessed February 23, 2015.

Centers for Disease Control. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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