

Subject: **Veterinary Care** **Policy #3**
Expired Medical Materials
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References: AWA Section 13
9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40
9 CFR, Part 3, Section 3.110

History: Provides requested guidance. Replaces memoranda dated May 31, 1990, November 29, 1991, April 6, 1992, and September 25, 1992. The previous version of this policy released on April 14, 1997, has been modified to include "Health Records."

Justification: The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.

Policy: **Expired Medical Materials**

The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. The Animal & Plant Health Inspection Service (APHIS) has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities.

For acute terminal procedures, APHIS does not oppose the use of expired medical materials if their use does not adversely affect the animal's well-being or compromise the validity of the scientific study. Proper anesthesia, analgesia, and euthanasia are required for all such procedures. Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their

expiration date. 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. These responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.

Pharmaceutical-Grade Compounds in Research

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical-grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

Surgery

AWA regulations require that survival surgeries be performed using aseptic techniques and that major operative procedures on nonrodents be performed only in dedicated surgical facilities. Nonsurvival surgeries require neither aseptic techniques nor dedicated facilities if the subjects are not anesthetized long enough to show evidence of infection. Research facilities doing surgical demonstrations while traveling must use aseptic techniques and dedicated surgical facilities. Motel meeting rooms and auditoriums do not qualify as dedicated surgical facilities.

Nonsurvival surgeries not performed aseptically or in a dedicated facility must at least be performed in a clean area, free of clutter, and using acceptable veterinary sanitation practices analogous to those used in a standard examination/treatment room. Personnel present in the area must observe reasonable cleanliness practices for both themselves and the animals. Eating, drinking, or smoking are not acceptable in surgery areas, and locations used for food handling purposes do not qualify as acceptable areas for performing surgeries.

Pre- and Post-Procedural Care

All animal activity proposals involving surgery must provide specific details of

pre- through post-procedural care and relief of pain and distress. The specific details must be approved by the attending veterinarian or his/her designee. However, the attending veterinarian retains the authority to change post-operative care as necessary to ensure the comfort of the animal. The withholding of pain and/or distress relieving care must be scientifically justified in writing and approved by the IACUC. The appropriate use of drugs to relieve pain and/or distress must be specified in the animal activity proposal to avoid possible delays due to investigator concerns that a treatment regimen may interfere with the study. Furthermore, the specified drugs for relief of pain and/or distress must be readily available for use as described in the proposal.

While an animal is under post-surgical care, the ownership of the animal is not to change. If the animal is taken to an off-site location, such as a farm, for post-operative care, that location should be identified as a site of the research facility. An animal is not to be taken to an off-site location before it fully recovers from anesthesia unless justified in the animal activity proposal. Appropriate post-operative records must be maintained in accordance with professionally accepted veterinary procedures regardless of the location of the animal.

Program of Veterinary Care

Facilities which do not have a full-time attending veterinarian must have a written Program of Veterinary Care (PVC). This Program must consist of a properly completed APHIS Form 7002 or an equivalent format providing all of the information required by the APHIS form. The attending veterinarian must visit the facility on a regular basis, i.e., often enough to provide adequate oversight of the facility's care and use of animals but no less than annually. Records of visits by the attending veterinarian must be kept to include dates of the visits and comments or recommendations of the attending veterinarian or other veterinarians.

The PVC must be reviewed and updated whenever necessary (e.g., as a new species of animal or a new attending veterinarian is obtained, or the preventive medical program changes). It must be initialed and dated by both the attending veterinarian and the facility representative whenever it is changed or reviewed without change. The preventive medical program described in the PVC is expected to be in accordance with common good veterinary practices (e.g., appropriate vaccinations, diagnostic testing). It should include zoonotic disease prevention measures and, if necessary, special dietary prescriptions.

Health Records

Health records are meant to convey necessary information to all people involved in an animal's care. Every facility is expected to have a system of health records sufficiently comprehensive to demonstrate the delivery of adequate health care. For those facilities that employ one or more full-time veterinarians, it is expected there will be an established health records system consistent with professional standards that meets and probably exceeds, the minimum requirements set forth in this policy. For facilities that do not employ a full-time veterinarian, it is suggested the health records system be explained as part of the written PVC, to ensure involvement of the attending veterinarian in developing the system. For all facilities, health records must be current, legible, and include, at a minimum, the following information:

- ! Identity of the animal.
- ! Descriptions of any illness, injury, distress, and/or behavioral abnormalities and the resolution of any noted problem.
- ! Dates, details, and results (if appropriate) of all medically-related observations, examinations, tests, and other such procedures.
- ! Dates and other details of all treatments, including the name, dose, route, frequency, and duration of treatment with drugs or other medications. (A "check-off" system to record when treatment is given each day may be beneficial.)
- ! Treatment plans should include a diagnosis and prognosis, when appropriate. They must also detail the type, frequency, and duration of any treatment and the criteria and/or schedule for re-evaluation(s) by the attending veterinarian. In addition, it must include the attending veterinarian's recommendation concerning activity level or restrictions of the animal.

Examples of procedures which should be adequately documented in health records include, but are not limited to, vaccinations, fecal examinations, radiographs, surgeries, and necropsies. Routine husbandry and preventive medical procedures (e.g., vaccinations and dewormings) performed on a group of animals may be recorded on herd-health-type records. However, individual treatment of an animal must be on an entry specific to that animal. As long as all required information is readily available, records may be kept in any format convenient to the licensee/registrant (e.g., on cage cards for rodents).

Health records may be held by the licensee/registrant (including, but not limited to, the investigators at research facilities) or the attending veterinarian or divided between both (if appropriately cross-referenced), but it is the responsibility of the licensee/registrant to ensure that all components of the

records are readily available and that the record as a whole meets the requirements listed above.

An animal's health records must be held for at least 1 year after its disposition or death. (Note: Some records may need to be held longer to comply with other applicable laws or policies.) When an animal is transferred to another party or location, a copy of the animal's health record must be transferred with the animal. The transferred record should contain the animal's individual medical history, information on any chronic or ongoing health problems, and information on the most current preventive medical procedures (for example, the most recent vaccinations and dewormings). For traveling exhibitors, information on any chronic or ongoing health problems and information on the most current preventive medical procedures must accompany any traveling animals, but the individual medical history records may be maintained at the home site.

Euthanasia

The method of euthanasia must be consistent with the current Report of the AVMA Panel on Euthanasia. Gunshot is not an acceptable method of routine euthanasia for any animal. Gunshot as a routine method of euthanasia not only endangers surrounding animals, buildings, and personnel, but it is likely to cause distress to other animals. It should only be used in situations where other forms of acceptable euthanasia cannot be used (such as emergency or field conditions where the animal cannot be appropriately restrained) or in cases where gunshot will reduce danger to other animals or humans. Only personnel skilled in the use of firearms, using appropriate firearms, and familiar with the "kill point" of an animal should perform the euthanasia. If the firearm is not aimed so that the projectile enters the brain and causes rapid unconsciousness and subsequent death without evidence of pain or distress, this method does not meet the definition of euthanasia. (All State and local laws relevant to gunshot must also be met.)