Policy #3: Veterinary Care:	
Expired Medical Materials Pharmaceutical-Grade Compounds in Research Surgery Pre- and Post- Procedural Care Program of Veterinary Care Declawing and Defanging Practices in Wild or Exotic Carnivores or Nonhuman Primates Health Records Euthanasia	Change to: Pharmaceutical-Grade Substances in Research
Issue Date: March 25, 2011	Change to: XXXXX, 2013
References: AWA Section 2143 9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40 9 CFR, Part 3, Section 3.110	No Change
History: Replaces memoranda dated May 31, 1990; November 29, 1991; April 6, 1992; and September 25, 1992. Replaces policies dated April 14, 1997; January 14, 2000; August 18, 2006; and July 17, 2007.	Add: September XXX, 2013
Justification: Provides requested guidance. The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.	No Change
Policy: Expired Medical Materials	Change to:
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.	The use of expired medical materials (e.g., drugs, fluids, sutures, anesthetics, or analgesics) during any surgical procedure is not considered acceptable veterinary practice and therefore not consistent with adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. However, expired medical materials except analgesics, anesthetics, and euthanasia solutions may be used in acute terminal procedures where an animal is anesthetized during the study and euthanized without recovery if such use does not adversely

The Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities.

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.

affect the animal's well-being or compromise the validity of the scientific study.

Facilities permitting the use of expired medical materials in acute terminal procedures should have a policy on the use of such materials and/or require investigators to describe the intended use in the animal study proposal.

The Animal and Plant Health Inspection Service/ Animal Care (APHIS/AC) has determined that the attending veterinarian along with the IACUC should control the use of expired medical materials in order to comply with the regulatory requirement to ensure pain and distress is minimized during proposed activities.

Expired materials should be segregated from non-expired medical materials in an appropriately labeled, physically separate location or discarded. APHIS however has no jurisdiction over the possession and use of expired medical materials for non-regulated animals and activities.

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 is not a justification for using non-pharmaceutical-grade compounds in regulated animals.

<u>Change to</u>: Pharmaceutical-Grade Substances in Research

Investigators are expected to use pharmaceutical-grade substances whenever they are available, even in acute procedures. This includes but is not limited to: compounds, medications, drugs, vehicles, and diluents. Non-pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC. The IACUC should develop a consistent evaluation process which includes but not limited to the scientific justification and the availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone is not sufficient

	justification for using a non-pharmaceutical-grade substance in regulated animals. APHIS recognizes that most test articles and novel compounds are by definition not available in pharmaceutical grade. Consultation with the attending veterinarian and consideration of alternatives are required when procedures that use non-pharmaceutical grade substances may potentially cause more than slight or momentary pain or distress.
Surgery	Surgery ADD: Professional Standards and Established Procedures: Current professional standards preclude eating, drinking, or smoking in surgery areas. Locations used for food handling purposes do not qualify as acceptable areas for performing surgeries.
Survival Surgeries: 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. For the purposes of this policy, designated surgical facilities are those that are set up to be cleaned and maintained in an aseptic condition, and are not used for other purposes when they are not being used for surgery. They must be maintained in good repair to meet aseptic requirements.	No Change
APHIS has determined that motel meeting rooms and auditoriums do not qualify as dedicated surgical facilities.	Change to: APHIS has determined that hotel meeting rooms and auditoriums do not qualify as dedicated surgical facilities.
Nonsurvival Surgeries: Nonsurvival surgeries do not require aseptic techniques or dedicated facilities but should be performed in a clean area, free of clutter, and using acceptable veterinary sanitation practices equivalent to those used in a standard examination/treatment room. Personnel present in the area should observe reasonable cleanliness practices for both themselves and the animals.	No Change

Current professional standards preclude eating, drinking, or smoking in surgery areas, and locations used for food handling purposes do not qualify as acceptable areas for performing surgeries.	Add: The performance of nonsurvival surgeries in hotel meeting rooms and auditoriums as practiced in instances such as teaching situations and demonstration can only occur provided the requirements for nonsurvival surgery and minimizing pain and distress are met. The change: paragraph moved to the beginning of the surgery section.
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 principal investigator must involve the attending veterinarian or his/her designee in planning the type of care that may be provided. The appropriate use of drugs to relieve pain and/or distress should 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. However, the attending veterinarian retains the authority to alter post-operative care if unexpected pain and/or distress occur in an animal. The IACUC must approve a significant change to the protocol if the attending veterinarian requests to alter post-operative care for the remaining animals. The withholding of pain and/or distress relieving care must be scientifically justified in writing and approved by the IACUC.	No Change
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 or a site of another registered research facility in order for AC to conduct an inspection.	Change to: In the event 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 or a site of another registered research facility in order for AC to conduct an inspection.
To comply with adequate veterinary care requirements and in accordance with currently accepted standards of practice, 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	No Change

post-operative records should be maintained in	
accordance with professionally accepted veterinary	
procedures regardless of the location of the animal.	
Program of Veterinary Care	No Change
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.	
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. APHIS	
recommends this visit occur at least annually. Records of	
visits by the attending veterinarian should be kept to	
include dates of the visits and comments or	
recommendations of the attending veterinarian or other	
veterinarians.	
The PVC should be reviewed and updated whenever	
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necessary (e.g., as a new species of animal or a new	
attending veterinarian is obtained, or the preventive	
medical program changes). APHIS recommends that the	
PVC 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 professionally accepted veterinary	
practice (e.g., appropriate vaccinations, diagnostic	
testing). It should include zoonotic disease prevention	
measures	
Declawing and Defanging Practices in Wild or Exotic	No Change
Carnivores or Nonhuman Primates	
Declawing of wild and exotic carnivores and the removal	
or reduction of canine teeth in nonhuman primates and	
wild and exotic carnivores have been used in the past in	
an attempt to minimize dangers presented during human	
interaction with these species. These procedures are not	
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innocuous and can cause ongoing pain, discomfort, or	
other pathological conditions in the animals. In addition,	
they do not prevent predatory behaviors, safeguard the	
general public, or prevent biting in nonhuman primates	
and carnivores.	
	Change to: The declawing of any wild or exotic
The declawing of any wild or exotic carnivore does not	carnivore does not constitute appropriate
constitute appropriate veterinary care. Any medical	veterinary care unless prescribed by the
treatment of a paw should be limited to the affected	attending veterinarian for treatment of
digit(s) or area and should not require bilateral	_
	individual medical problems of the paws. Any

declawing.	medical treatment of a paw should be limited to the affected digit(s) or area.
The removal of the canine teeth of a nonhuman primate, or wild or exotic carnivore, unless for the immediate medical needs of the animal does not constitute appropriate veterinary care.	Change to: The removal of the canine teeth of a nonhuman primate, or wild or exotic carnivore, does not constitute appropriate veterinary care unless as prescribed by the attending veterinarian for the immediate medical needs of the animal.
Tooth reduction that exposes the pulp cavity does not constitute appropriate veterinary care as it may result in oral pathologic conditions and pain. Reduction that does not expose the pulp cavity may be acceptable in some instances such as a behavioral study or breeding situation.	No Change
The American Veterinary Medical Association (AVMA) has developed a policy statement on these issues that supports APHIS' recommendation. It also suggests alternatives to dental surgery such as behavioral modification, environmental enrichment, and changes in group composition. A full text of AVMA policies can be found on www.avma.org.	No Change
Health Records Health records are needed to convey necessary information to all people involved in an animal's care. Every facility should have a system of health records sufficiently comprehensive to demonstrate the delivery of adequate health care.	No Change

<u>Change to:</u> The method of euthanasia should be consistent with the current AVMA Guidelines for the Euthanasia of Animals: https://www.avma.org/KB/Policies/Pages/Euthanasia-Guidelines.aspx .
No Change
Change to: This method is conditionally acceptable under a specific set of circumstances in order to ensure the welfare of the animal undergoing euthanasia. Such circumstances include instances where other forms of acceptable euthanasia cannot be used (e.g. emergency or field conditions where the animal cannot be appropriately restrained) or includes situations where gunshot reduces the danger to other animals or humans. Only personnel skilled in the use of firearms, using appropriate firearms, and familiar with the "kill point" of the 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, the definition of euthanasia is not met. However, it may not be appropriate to target the head when samples of brain tissue are needed, hence gunshot through the heart may be necessary in such situations. Note: All State and local laws relevant to gunshot must also be met.
No Change