

Standard Operating Procedure

Expired Medical Materials

The Animal Welfare Act (9 CFR Part 2, subpart C [sections 2.31-2.33] and subpart D [section 2.40]) and Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals require the provision of adequate veterinary care, to be overseen by the Attending Veterinarian and IACUC. The United States Department of Agriculture (USDA) Animal Care Policy #3 <http://www.aphis.usda.gov/ac/policy3.html> indicates specifically, “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.” The Office for Laboratory Animal Welfare (OLAW) provides similar requirements <http://grants.nih.gov/grants/olaw/faqs.htm>

The use of expired pharmaceuticals, biologics, and supplies is not consistent with acceptable veterinary practice or adequate veterinary care. It is unacceptable to use expired euthanasia, anesthesia, and analgesic agents 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. The university veterinarian and IACUC must maintain control over the use of expired medical materials used on animals in order to meet their responsibilities to avoid or minimize discomfort, pain or distress to animals.

Drug Bottles Made In-House

When drugs are aliquoted, diluted, or mixed into cocktails, or dispensed by the core animal facility (BRSF) so that they are no longer in manufacturer’s bottles they must be marked with the expiration date of the soonest expiring component, the name of the drug(s) and the concentration(s). These mixtures and aliquots expire on the date of the soonest expiring component unless data indicates otherwise.

Aseptic Technique When Using Septum Vials

Needles, syringes and vials used for sterile injectable drugs must be sterile. It is recommended that sterile injectable drugs be used even in non-survival procedures as rapidly occurring inflammatory reactions to microbes can affect research outcomes. Used or contaminated (by touching anything non-sterile) needles must never be inserted through the septum of a sterile drug vial. The septum of sterile drug vials should be wiped with alcohol before needle insertion.

Stability of IV Fluids

IV fluid bags come packaged in different sizes, and with an outer plastic wrapping. If the bags are stored with this outer wrapping intact the fluids are considered stable until the expiration date that is imprinted on the bag by the manufacturer. Depending on the size of the IV fluid bag, once the IV fluid bag is removed from its outer wrapper the fluids are considered stable for: **15 days, if the IV bag is 50ml or smaller and 30 days, if the IV fluid bags are 100ml or larger**. This is only if the bags are being stored without being used and they have been removed from their outer wrappers.

According to CDC (Center for Disease Control) guidelines, once any IV fluid bag is spiked (an IV drip set inserted into the bag for fluid delivery), or if a needle has been inserted into the injection port for any reason, the fluids are considered stable for only 24 hours. Any IV fluid bag that has been infiltrated should be labeled with the date and time of initial use and discarded after 24 hours. Do not write directly on the bag of fluids with any type of pen as some inks have been known to leach through the plastic and into the fluids. Write any needed information on labels or tape first, then affix to the bag.

Items Sterilized In-House

Items sterilized in-house must have an external process indicator (e.g., autoclave tape). Cloth-wrapped, paper wrapped, and plastic wrapped items sterilized in-house are considered sterile for six months from the date of sterilization if stored unopened, as long as the package is not compromised by opening, wetting, or damage. Items autoclaved in peel pouches are considered sterile up to one year from the date of sterilization, as long as the package is not compromised by opening, wetting, or damage. The function of autoclaves used to sterilize surgical items must be tested at least once per month with commercially made biological spores.

REFERENCES:

OLAW FAQ #5: May investigators use expired pharmaceuticals, biologics, and supplies in animals?
<http://grants.nih.gov/grants/olaw/faqs.htm>

USDA Animal Care Policy, Animal Care Resource Guide, Issue Date: July 17, 2007
http://www.aphis.usda.gov/animal_welfare/downloads/policy/policy3.pdf

US Pharmacopeia (USP) and the National Formulary (NF) combined standards compendia available at <http://www.usp.org/usp-nf>