

Guidelines for the Oversight of Multi-Use Drug Vials in Animal Research

I. Purpose:

The purpose of this document is to define requirements to minimize the likelihood of contamination with multi-use drug vials used in animal research.

II. Introduction:

The Joint Commission has incorporated a 28-day expiration policy for multi-use drug vials into the accreditation and certification process, thus requiring accredited hospitals and organizations to comply with the 28 day rule. Since this rule involves products that are intended to be administered to human patients only and since the use of these products can vary significantly in animal research, it does not apply when multi-use drugs are administered to animals.

However, even though Animal Researchers do not abide by this 28 day rule, ensuring the sterility of multi-use drug vials is critical to performing sound research.

III. Guidelines for Multi-Use Drug Vials:

The following standards must be adhered to when using drugs dispensed in multi-use containers in animal research:

- 1) The drug must be disposed of at the manufacturer's listed expiration date.
- 2) The vial once opened should be stored per manufacturer's recommendations.
- 3) When multiple penetrations of a vial stopper or diaphragm must occur, the surface should be disinfected with 70% alcohol before each penetration.
- 4) A sterile needle and syringe must be used for each vial entry.
- 5) If the content of a multi-use drug vial shows evidence of abnormal torpidity, discoloration, particulates, or other changes suggesting compromised sterility, it should be disposed of appropriately.
- 6) Unanticipated injection site reactions suggesting possible contamination should be reported to the Animal Research Facility Supervisor (412-360-6107).