

A. Column E Explanation

Two non-human primates developed acute complications while on a toxicology study and died before euthanasia could be accomplished.

Two guinea pigs died while on product release testing studies for vaccines and biologics. One guinea pig developed acute terminal complications and died before euthanasia could be accomplished. The other guinea pig died unexpectedly and did not have any clinical signs prior to death.

Four rabbits developed acute complications while on a toxicology study and died before euthanasia could be accomplished.

The activities and procedures of conduct for the above-referenced studies were reviewed and approved by the Institutional Animal Care and Use Committee (IACUC). Animals used on product release testing and toxicology studies were required by federal regulations for submission regarding safety and toxicity testing. The regulations that require these procedures include 21 CFR 58 (FDA) and 21 CFR 610.11 (FDA).

B. Summary of exceptions to the regulations and standards

Exceptions to § 3.76 - Indoor housing facilities. (c) Lighting

Nineteen non-human primates were considered as exceptions to the regular diurnal lighting schedule for the conduct of a cognition study. There were 48 occurrences where the light cycle was changed from a 12h:12h schedule to a 15h(on):12h(off) or 9h(on):12h(off). **The IACUC approved these exceptions based on scientific justification.**

Exceptions to § 3.10 – Watering

Twenty-three beagle dogs were considered as exceptions to the continuous access to water for a biopharmaceutical study. There were 2 to 10 occurrences of water being withheld for 1 hour prior to administration of compound. **The IACUC approved these exceptions based on scientific justification.**