

**B. Summary of exceptions to the regulations and standards October 1, 2018 - September 30, 2019**Exceptions to the standard 2-week cage sanitation program

Six non-human primates were considered as exceptions to the standard 2-week complete cage sanitation program for the conduct of telemetry data collection studies. There was one (1) occurrence with two non-human primates and two (2) occurrences with one non-human primates where the sanitation was extended between 17 to 20 days. However, the standard daily cleaning of the cages was maintained during this period. The IACUC approved these exceptions based on scientific justification.

Twelve non-human primates were considered as exceptions to the standard 2-week complete cage sanitation program for the conduct of long-acting radio-isotope collection studies. There was on (1) occurrence with ten non-human primates and two (2) occurrences with 2 non-human primates where the sanitation was extended to 30 days. However, the standard daily cleaning of the cages was maintained during this period. The IACUC approved these exceptions based on scientific justification.

**A. Column E Explanation (all studies listed below were approved by the IACUC at their respective site):**

One rabbit developed per acute complications while on a toxicology study and died before euthanasia could be accomplished.

One non-human primate 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 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).

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