

QUALITY ASSURANCE

This category deals with the licensing, importation, and testing of veterinary biologics for purity, safety, potency, and efficacy in accordance with the Virus-Serum-Toxin Act.

DISPOSAL AUTHORITY NI-0463-95-3

*** Retention Period ***

QA 1 REFERENCE FILES

Copies of regulations, memoranda, correspondence, reference requests, and the results of special searches.

(item 3007a)

Originating office:

Destroy when no longer needed for reference.

(item 3007b)

All other offices:

N/A

QA 2 REPORTS AND STATISTICS

Reports covering all subjects included under this primary subject. Case filed by type of report.

(item 3008a)

Originating office:

Destroy when no longer needed for legal (per 40 CFR Part 160) or administrative purposes.

Reports of periodic inspections of studies showing the date of inspection, study inspected, phase or segment of the study inspected, findings recommended, actions scheduled, reinspection, and name and signature of inspector. Case filed by study.

(item 3008a)

All other offices:

N/A

*** Retention Period ***

**QA 3 STANDARD OPERATING PROCEDURES
(SOP's)**

a. Data base Tracking System of the following information for active and canceled SOP's: Title, Author, Originating Section, Preparation Date, Revision Number and Date/Authors and Preparation Date.

(Item 3009a)
Originating office:
Destroy when no longer needed for administrative purposes.

(Item 3009b)
All other offices:
N/A

b. Working file consisting of the most current SOP version and correspondence relative to the development of the SOP, with comments by staff scientists reviewing the SOP.

(Item 3010a)
Originating office:
Destroy when superseded obsolete.

(Item 3010b)
All other offices:
N/A

c. Historical file of all standard operating procedures and all revisions approved for use by the institution.

(Item 3011a)
Originating office:
Destroy when no longer needed for legal (per 40 CFR Part 160) or administrative procedures

(Item 3011b)
All other offices:
N/A

*** Retention Period ***

QA 4 MASTER SCHEDULE

Master schedule of all studies conducted at the testing facility, indexed by test substance and containing the test system, nature of the study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director.

(Item 3012a)

Originating office:

Destroy when no longer needed for legal (per 40 CFR Part 160) or administrative purposes.

(Item 3012b)

All other offices:

N/A

QA 5 PROTOCOLS

Working copies of Good Laboratory Practices protocols pertaining to studies for which the unit is responsible.

(Item 3013a)

Originating office:

Destroy when no longer needed for legal (per 40 CFR Part 160) or administrative purposes.

(Item 3013b)

All other offices:

N/A

QA 6 MAINTENANCE AND CALIBRATION OF EQUIPMENT

Information on the inspection, maintenance, testing, calibration, and standardization of equipment.

a. Computer Data Base. Contains maintenance schedules only.

(Item 3014a)

Originating office:

Delete when no longer needed for administrative purposes.

(Item 3014b)

All other offices:

N/A

*** Retention Period ***

QA 6 *(continued)*

b. Paper Records. Original correspondence relating to maintenance and calibration of equipment, test results, and the date and place of equipment tested.

(Item 3015a)

Originating office:

Destroy when no longer needed (per 40 CFR Part 160) or administrative purposes.

(Item 3015b)

All other offices:

N/A