Toxikon Corporation

Bedford MA 01730

**STANDARD OPERATING PROCEDURE**

Reference Number: \*\*\*\*\*\*

Revision Number: 000

**New SOP\*\*\*\*\*\*\*\*\***

1. **PURPOSE**

State the purpose or intended use.

1. **MATERIALS**
2. **PROCEDURES**
3. **EVALUATION**

If applicable

1. **RECORDS**
   1. Data Recording Requirements

All activities must be recorded at the time of occurrence. Data collection forms and/or SOP related work forms and/or electronic data collection must be completed, and signed by technically competent and responsible personnel, as per Study Director SOP 1.5.21, current revision.

* 1. Archivable Data

All raw data, including ancillary data (e.g., equipment calibration forms, etc.) are to be archived according to SOPs 1.5.5, 1.5.5.1, and 1.5.5.4, current revisions, if applicable.

Records of archive activities are maintained in Lotus Notes or Matrix Gemini (SOP 15.3.9 and 15.3.17, current revisions), or other Software Systems, where applicable.

1. **SAFETY PRECAUTIONS AND PERSONAL PROTECTIVE EQUIPMENT (PPE) REQUIREMENTS**

The standards contained within Toxikon's Chemical Hygiene Plan apply, unless there are project or substance related specialized precautions, which would be provided in writing to the Study Director and staff for additional exposure assessment and training.

**Location:** Not applicable

Risk Level: Not applicable

Required PPE: Not applicable

Special Precautions: Not applicable

1. **REFERENCES**
   1. Technical Guidelines

Not applicable

* 1. Supplementary Standards

ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories.

* 1. Published Literature

Not applicable

1. **FORMS / ATTACHMENTS**
   1. There are no specific forms in this SOP **or** see Attachment I, Attachment II, etc.
2. **RESPONSIBLE / ALTERNATE PERSONNEL**

Personnel should be identified to the department/role level as responsible for the use and operation of this SOP.

1. **CROSS REFERENCED SOPs**

1.5.5 Storage and Retrieval of Records and Data

1.5.5.1 Quality Records

1.5.5.4 Storage, Retrieval, and Archive Management of Electronic Study Records

1.5.21 Study Director

15.3.9 Workflow Databases

15.3.17 Matrix Gemini Laboratory Information Management System