Chemistry Specifications for Chemistry Services Contractors

National Toxicology Program

Appendix 4.2. Data Submission Requirements

Final

August 11, 2016

1. *General Requirements*
    1. Submitted data shall be tabulated.
    2. Tables shall include a header that describes the study from which the samples used to generate the data were obtained. Information that must be present in the header includes, but is not limited to:
        1. Animal data: Species, strain, sex, and age of the sample source animals.
        2. Study data: Study lab, study identifier (when available)
        3. Chemical data: Chemical name, CAS reference number
        4. Sample data: Matrix (or vehicle); type(s) of samples for which results are being reported, e.g., plasma, amniotic fluid, etc.; number of samples of each type received; receipt date; and analysis date(s).
    3. Time-course data shall include a list of animal numbers and associated species/strain/sex of the animal, and the time point at which the sample was collected.
    4. A summary of the method used to generate the data shall be included in the same file as the data.
    5. The interim data file shall be uploaded to the NTP IMS and attached to the assignment that generated the data.
2. *Interim Data Requirements*
    1. Interim data may be submitted in Microsoft Word™ or Excel™ formats or as a PDF file; depending on the data type. Except as described below, the file format shall be selected to best present the data.
        1. Biosample method validation and analysis results; and formulation validation and time course data shall be submitted in Excel™ format.
        2. Dose analysis results shall be submitted in Word™ format.
        3. Chemical characterization data may be submitted in Word™ or PDF format.
    2. 508-compliance is not required for interim data submissions.
    3. Interim data shall undergo a quality control (QC) check prior to submission, but does not require quality assurance (QA) review.

3. *Final Data Requirements*

    1. When a final data submission is required (Section 4. Reporting Requirements and Deliverables) for a selected assignment type all data shall undergo QA review prior to submission.
    2. Final data may be submitted in Microsoft Word™ or Excel™ formats or as a PDF file; depending on the data type. Except as described below, the file format shall be selected to best present the data.
        1. Biosample analysis results and time course data shall be submitted in Excel™ format.
        2. Dose analysis results shall be submitted in Word™ format.
        3. Chemical characterization data may be submitted in Word™ or PDF format.
    3. Final data submissions must be Section 508 compliant.

4. *Excel™ File Format*

    1. Tab 1 shall include all of the header information described above.
        1. Excel™ spreadsheets for time-course data shall also include the animal number information described above.
    2. Tab 2 shall include the method summary.
    3. Tab 3 et seq. shall include results for each species, strain, and sex for which samples were analyzed.
        1. Data shall be organized so that data for only one species/strain/sex and dose is presented on each tab.
        2. Each tab shall contain header information with the study, species/strain/sex data presented on the tab, sample receipt dates, analysis dates, ChemTask number, and lab SOP or AM number used for the analysis.
        3. Tabs shall be labeled with the species-sex, and dose of the sample results presented on the tab, e.g., M-mouse 500 mg/kg.