

Chemistry Specifications for Chemistry Services Contractors

National Toxicology Program

Special Studies

Final

August 11, 2016

1. Special Chemical Activity (SCA)

1. When a requirement necessitates a deviation from the descriptions for a functional activity, but falls within the scope of work given in the contract, the COR shall direct the contractor to perform a Special Chemical Activity.
2. Examples of work that may be performed under this functional activity include, but are not limited to:
 1. Studies on the rate of loss of test chemical from solvents or dosing vehicles.
 2. Studies of complex mixtures.
 3. Procurement of microencapsulated chemicals.
 4. Particle size reduction to submicron diameters.
 5. Forced degradation studies of a test article.
 6. Activities that are combinations of some or all of two or more functional activities e.g., a formulation analysis that includes a validation to cover a lower concentration, which is a combination of parts of the formulation and formulation development and validation assignment types.
 7. Activities that cover a subset of a functional activity, or which falls within the scope of the functional activity, but does not include all of the activities described for that functional activity e.g., performing a comprehensive chemical analysis without an accelerated stability study component.
3. When any SCA assignment is performed, the requirements and scope of the work will be assigned by the COR and described in the NTP IMS.
4. The contractor shall report the work done in this functional activity following the reporting requirements given in Section 4. Reporting Requirements.

2. Special Inhalation Studies (SIS)

1. As directed by the COR, the Contractor shall determine the feasibility of generating a specified atmospheric concentration of a test article. This evaluation may include, but is not limited to, one or more of the following.
 1. The Contractor shall characterize the test article prior to its use in any Special Inhalation Study.
 2. The Contractor shall investigate the production of a homogeneous atmosphere using a chemical specified by the COR and an appropriate generation system and chamber.
 3. The Contractor shall collect samples and perform analyses to determine the concentration of a test article in an exposure chamber

4. The Contractor shall determine the degree to which a test article tends to polymerize under conditions required to generate a vapor.
5. The Contractor shall determine the purity profile for the vapor phase of a test article in the chamber and the unvaporized test article.
2. When Special Inhalation studies involve the use of animals, the Contractor shall submit their approved IACUC protocol to the COR prior to ordering animals.
3. The contractor shall report the work done in this functional activity following the reporting requirements given in Section 4. Reporting Requirements.

3. *Annual Water Analysis (AWA)*

The Contractor shall demonstrate that water provided for laboratory animal use meets U.S. EPA drinking water standards. To satisfy this requirement, the Contractor shall provide analyses of water used in the laboratory at least once per year. A list of water components and contaminants to be determined are given below. Contractors shall specify whether they use distilled water and/or filtered water. A laboratory qualified to conduct such studies on a local, state, or interstate level shall perform water analyses.

1. Objectives

1. To determine the level of potential contaminants in water used by the Contractor.

2. Requirements

1. The contractor must provide analyses of water from an animal room or a composite from several animal rooms at least once per year.
2. The contractor must specify whether they use distilled water and/or filtered water.
3. A laboratory qualified to conduct such studies on a local, state, or interstate level shall perform water analyses.
4. The contractor shall report values for, at minimum, all of the following parameters:
 1. Total dissolved solids (mg/L), including:
 1. Sodium, Potassium, Magnesium, Calcium, Strontium, Barium, Boron, Aluminum, Phosphorus, Chromium, Manganese, Iron, Copper, and Zinc
 2. Heavy metals, (ng/L) including:
 1. Arsenic, Cadmium, Lead, and Mercury
 3. Chlorinated hydrocarbons (mg/L), including:

1. Aldrin, Dieldrin, Endrin, Heptachlor epoxide, Lindane (gamma-BHC), Chlordane, DDT Related Substances, and PCB (Arochlor)
 4. Organophosphates (mg/L), including:
 1. Thimer® (Phorate), Diazinon, Methyl parathion, Malathion, Parathion, Thiodan (Endosulfan I and II), and Thrithion (Carbophenothion)
 5. Nitrate (mg/L)
 6. Nitrite (mg/L)
 7. Microbiological content, including standard plate count CFU/mL
 8. Total trihalomethanes (mg/L)
3. The contractor shall report the work done in this functional activity following the reporting requirements given in Section 4. Reporting Requirements.