

Chapter 2. Facilities

**Specifications for the Conduct of Chemistry Activities for Toxicology
Research Performed by the
Division of Translational Toxicology at the
National Institute of Environmental Health Sciences**

2. Facilities

Bradley J. Collins¹, Suramya Waidyanatha¹ (Editors)

¹Division of Translational Toxicology, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, USA

Last Updated: May 2026

2.1. General Requirements

The contractor shall provide floor plans that show the locations where all program activities will be conducted. Plans shall show quality assurance (QA) offices and filing space, data archives, waste storage, and study facilities. Floor plan requirements for specific program areas are provided below.

The contractor shall provide a secured, limited access area for maintenance of all study and QA records.

2.2. Emergency Facility Support

Facilities shall have a tested back-up power source with automatic changeover equipment that is sufficient to preserve the integrity of ongoing work (e.g., animal studies, stored test articles, biological samples).

Emergency power must be enabled for those areas critical to the program such as animal rooms, heating, ventilation, and air conditioning (HVAC), storage freezers/refrigerators, and waste storage.

Essential mechanical equipment must be guarded or alarmed. Provisions for prompt maintenance response must be provided. Alternative air handling systems for inhalation studies are required.

2.3. Animal Facilities

All animal facilities used for this program must be approved by the Division of Translational Toxicology (DTT) and will be evaluated with respect to criteria outlined in the following documents:

- Guide for the Care and Use of Laboratory Animals (National Research Council) and any other additions and exceptions thereof (NIH 2011)
- Public Health Service Policy on Humane Care and Use of Laboratory Animals, NIH Office of Laboratory Animal Welfare (NIH 2015)

Research shall be conducted in accordance with the Public Health Services Policy on Humane Care and Use of Laboratory Animal Welfare from the Office of Laboratory Animal Welfare (NIH 2015). Accreditation of toxicology research and testing facilities by an external peer review organization such as the Association for Assessment and Accreditation of Laboratory Animal Care International or Canadian Council on Animal Care is required.

Chapter 2. Facilities (DTT Chemistry Specifications)

The contractor shall establish policy and procedures to address entry of approved staff and visitors into the animal facility. Entry shall be prohibited to individuals that have been in another animal facility within the last 48 hours regardless of the disease status of the other facility.

The animal facilities shall be designed and managed to prevent contamination of animals with pathogenic organisms, to prevent contamination of personnel and the environment with test articles, and to prevent cross-contamination of animals with other test articles.

The contractor shall provide a floor plan that indicates quarantine rooms, animal rooms, showers/change areas, and restrooms; storage areas for feed, bedding, and general storage; cage and rack washers; storage area for refrigerators and freezers; emergency power sources; and areas in which emergency power operates. This floor plan is to indicate traffic flow for personnel, animals, test articles, feed/bedding, supplies, and equipment through the facility.

A separate floor plan of the animal facility is to indicate room airflow directionality and indicate the location of all safety equipment, such as eyewash stations, safety showers, and control equipment.

A floor plan indicating ventilation equipment and ductwork, including interior and exterior exhausts, shall be supplied. A floor plan for the roof(s) shall indicate the location of each of the building(s) general air intakes and exhausts and the location of the exhaust for each hood or vented enclosure.

2.4. Chemistry Functional Areas

The contractor must have appropriate facilities and instrumentation required for activities under the statement of work. The specific types of analytical instrumentation required include, but are not limited to, gas and/or liquid chromatographs, with a variety of detectors (e.g., flame ionization, electron capture, mass spectrometry, ultraviolet/visible, nitrogen phosphorous, charged aerosol). Other instruments include, but are not limited to, infrared spectrophotometry, proton- and carbon-nuclear magnetic resonance (NMR) spectroscopy including multidimensional NMR techniques; scanning calorimetry, thermogravimetric analysis, and/or thin-layer chromatography and equipment required for determination of physical properties, e.g., boiling and/or melting point, density, and optical rotation. The contractor shall also have, in addition to some of the equipment mentioned above, high-resolution mass spectrometry systems.

The contractor shall have access to (via subcontract or cooperative agreement) appropriate facilities required for characterization of nonchemical test articles (e.g., asbestos, nanomaterials).

Floor plans shall be provided for all areas in the statement of work; supporting instrumentation and equipment; storage area for refrigerators and freezers; and exhaust hoods, including instrument placement, ventilation, airflow, and traffic patterns. Plans shall indicate the location of all safety equipment, such as eyewash stations, safety showers, and fire control equipment.

2.5. Hazardous Materials Handling and Hazardous Waste Storage

The contractor must have one or more controlled-access test article containment/dose preparation facilities suitable for handling neat chemicals and/or test articles. Please refer to Chapter 3. Health and Safety for additional safety requirements.

The containment facility shall include the following:

- Secured, controlled-access storage facilities for retention of the test article at $4^{\circ}\text{C} \pm 3^{\circ}\text{C}$ or at ambient temperature as specified by DTT. Test article storage includes storage of multiple 55-gallon drums. Cold storage at $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ must be available for analytical reference standards and some test articles (e.g., natural products). Secured cold storage facilities for retention of biological samples at ultracold temperatures (e.g., $\leq -70^{\circ}\text{C}$) are required.
- Suitable V-shell blenders with intensifier bars, to be used for feed formulation preparation.
- Designated areas for chemical handling, including repackaging, aliquoting, and preparation for shipment.
- Equipment needed for formulation preparation, including but not limited to, blenders, including Hobart™ blenders, homogenizers, mills, and shakers.
- Designated areas for hazardous waste storage, including formulation storage, prior to disposal.

The contractor shall establish policies and procedures to address entry of approved staff and visitors into the test article containment/dose preparation facility and for facility use and maintenance including:

- Appropriate monitoring of personnel entering and exiting the facility, including procedures to prevent contamination outside the containment facility by persons exiting the facility after handling neat chemicals or test articles.
- Personal protective equipment required while in the containment facility.

It is the responsibility of the chemistry contractor to establish policies and procedures to appropriately monitor ventilation systems, including hoods, HVAC, and high-efficiency particulate air filtration units.

The contractor shall provide a floor plan of the test article containment/dose formulation preparation area(s) for handling of neat chemicals and/or test articles, including storage areas for bulk test articles and dose formulations, supporting equipment and instrumentation, and exhaust hoods. The floor plan shall document instrument and equipment placement, ventilation, airflow, and traffic patterns. Plans shall indicate the location of all safety equipment, such as eyewash stations, safety showers, and fire control equipment.

2.6. References

National Institutes of Health (NIH), Office of Laboratory Animal Welfare (OLAW). 2015. Public health service policy on humane care and use of laboratory animals. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health. NIH Publication No. 15-8013.

<https://grants.nih.gov/grants/olaw/references/phspolicylabanimals.pdf>

National Research Council (NRC). 2011. Guide for the care and use of laboratory animals. 8th ed. Washington, DC: The National Academies Press. <https://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>