Chapter 1. General Personnel Requirements

Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences

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1. General Personnel Requirements

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This chapter describes requirements for personnel who conduct laboratory work for the Division of Translational Toxicology, National Institute of Environmental Health Sciences (DTT/NIEHS), including contractors and project staff. Although staff might have other responsibilities within the laboratory's organization, the amount of time devoted explicitly to contract/project activities shall be commensurate with the scale of the contract activities. Specific personnel requirements (i.e., personnel required and any additional requirements) will be defined in the contract. An overview of the requirements for key personnel or critical staff is presented in Table 1-1. Table 1-2 summarizes the general responsibilities of professional or technical support staff.

- Selected personnel categories are identified as key personnel, critical staff, or subject matter experts (SMEs). These categories are defined in the contract.
- The specific personnel fulfilling the roles of key personnel and critical staff will be named in the contract. Critical staff not employed by the prime contractor shall be included in the contract for named subcontractors. As appropriate, additional staff in critical roles shall be considered SMEs on a study-by-study basis.
- If a change is required in key personnel or critical staff, either through the employee no longer being employed by the contractor or because the employee is reassigned to another area within the organization, the contractor shall submit a candidate for replacement to the contracting officer’s representative for approval.
- For key personnel, advance notice of least 30 days is needed before diverting the individual to other programs or contracts (or as soon as feasible, if an individual must be replaced, for example, due to leaving the employ of the contractor). The contractor shall notify the contracting officer in writing and shall submit comprehensive justification for the diversion or replacement request to permit evaluation by the government of the effect on performance under this contract.
- SMEs shall be identified as needed for specific studies.
- Certain professional personnel are required to be employed by the contractor and cannot be consultants or subcontractors (see Table 1-1). The rationale for this requirement is that daily interaction and constant coordination are needed among these personnel throughout the execution phase of studies. This coordination makes it critical that personnel be physically and organizationally in the same location.
- For education/experience requirements, unless otherwise specified, the following combinations are considered equivalent. Table 1-1 expresses the preferred qualifications for a given personnel role; however, a suitable equivalent may be proposed by the contractor as needed.

  - Doctorate (Ph.D.) and 3 years of relevant experience, either through a postdoctoral program or work experience
  - Master's degree and 7 years of relevant experience
  - Bachelor's degree and 10 years of relevant experience
- Relevant discipline areas in the biological/physical sciences include degrees or significant relevant coursework, or both, in: toxicology, pathology, veterinary medicine, biochemistry, chemistry, pharmacology, anatomy, physiology, biology, biochemistry, embryology/developmental biology/endocrinology, neurotoxicology, psychology, and related areas.
- Relevant experience includes performance of a specific role(s), or that which prepares the individual to serve in a specific role(s) (e.g., experience as a study director prepares an individual to serve as a toxicology discipline leader).
- For personnel who have significant experience in a discipline area (e.g., a Ph.D. in an unrelated discipline +3 years of experience or no degree with >10 years of experience), the experience can serve as a substitute for the education requirements.

Table 1-1. Overview of Personnel Requirements for Professional Key Personnel/Critical Staff

Professional Staff	Responsibilities	Personnel Category[a]	Employee of Contractor	Education/Training/ Certification Requirements	Experience
Principal Investigator	Daily management of and point of contact for the contract; up-to-date knowledge of all aspects of the program/contracts to include study activities, cost, and schedule	Key	Required	Doctorate/10 years of experience in the biological/physical sciences or equivalent	Management of large-scale multidisciplinary programs, preferably rodent toxicology programs; demonstrated capability for oral and written communication (e.g., journal publications or lab reports)
General Toxicology Discipline Leader	Establish toxicology scientific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on studies/evaluations	Critical	Required	Doctorate/3 years of experience in the biological/physical sciences or equivalent; board certification (DABT) is preferred	Experience in the conduct of discipline-specific in vivo rodent toxicology studies; written communication (e.g., journal publications or lab reports)
Laboratory Animal Medicine Discipline Leader	Closely monitor the health of experimental animals; establish LAM-specific scientific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff (including other LAM veterinarians as applicable) on studies/evaluations involving issues related to animal care and medicine	Critical	Required	Doctorate (e.g., D.V.M.) from a veterinary medicine program recognized by the AVMA; diplomate (active or eligible) of the ACLAM is preferred	Experience in laboratory animal medicine and in managing large colonies of laboratory animals, in particular, rodents as part of multidisciplinary toxicology studies; if studies with dams/litters required, experience with breeding, pregnant and lactating animals, and fetuses/neonates/pups
Health and Safety Discipline Leader	Monitor worker health and safety conditions; has authority to bring unsafe conditions to the attention of upper management; reports to someone other than the principal investigator/study direction/conduct	Critical	Required	Bachelor's degree/3 years of experience or master's/1 year of experience in industrial hygiene, safety engineering or a related field; ongoing training at intervals not to exceed 1.5 years	Experience and training in occupational health and safety and hazard control, understanding of industrial hygiene; experience working with management and technical staff in implementing a health and safety program, including identification of problem areas and execution of corrective actions

Professional Staff	Responsibilities	Personnel Category[a]	Employee of Contractor	Education/Training/ Certification Requirements	Experience
Quality Assurance Unit Officer/ Discipline Leader	Monitor each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with applicable FDA GLP regulations (citation) and later interpretations; establish QA-specific guidelines and procedures; QA unit staff training; supervise, technically direct, and/or consult with appropriate professional and technical staff on matters related to QA; acts independently from personnel engaged in the principal investigator/study direction/conduct	Critical	Required	Bachelor's degree/10 years of experience in a biological/physical science or equivalent	Formal training/experience with conducting studies according to GLP regulations; experience to provide understanding of the tasks or reports being inspected or audited (e.g., chemistry, inhalation exposure, animal care, toxicology, pathology)
Inhalation Exposure Discipline Leader	Establish inhalation exposure-specific engineering and scientific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on the design, development, and fabrication of generation, monitoring, and exposure systems for inhalation studies	Critical	Required	Bachelor's/10 years of experience or master's/7 years of experience or equivalent in engineering or a related physical science or equivalent	Experience in designing and operating generators for maintaining stable inhalation chamber atmospheres for vapors, particulates, and/or liquid aerosols; experience in developing and operating a variety of monitoring systems for determining test article concentration in the test atmosphere; written communication (e.g., journal publications or lab reports)
Chemistry Discipline Leader	Establish chemistry-specific scientific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on analytical chemistry, dose formulation preparation/analysis, and (for inhalation studies) test atmospheres	Critical	Required	Master's/7 years of experience or doctorate/3 years of experience or equivalent in chemistry or a related physical science	Experience in dose formulation and analytical chemistry (i.e., identity, purity, and formulation analysis); for inhalation studies, experience in analyses of test agents in atmospheres; written communication (e.g., journal publications or lab reports)
Study Directors	Overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results; this shall include the direct observation of activities as required	Subject matter expert	Not required	Doctorate/3 years of experience or in the biological/physical sciences or equivalent; board certification (DABT) is preferred	Formal training/experience with conducting and reporting in vivo studies according to FDA GLP regulations; experience with study designs the individual will be responsible for; written communication (e.g., journal publications or lab reports)

Professional Staff	Responsibilities	Personnel Category[a]	Employee of Contractor	Education/Training/ Certification Requirements	Experience
Anatomic Pathology Discipline Leader	Establish guidelines and procedures for anatomic pathology; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on anatomic pathology techniques and evaluations	Critical	Not required	Formal training in a medical specialty (e.g., D.V.M. or M.D.); postdoctoral training and/or board certification in anatomic pathology (DACVP)	Experience in management of laboratory animal rodent pathology, particularly systemic neoplastic/nonneoplastic lesions or those of the reproductive and nervous systems; written communication (e.g., journal publications or lab reports)
Study Pathologists	Responsible for the histopathological evaluation and reporting of a study	Subject matter expert	Not required	Formal training in a medical specialty, (e.g., D.V.M. or M.D.); postdoctoral training and/or board certification in anatomic pathology (DACVP)	Experience in management of laboratory animal rodent pathology projects, particularly systemic neoplastic/nonneoplastic lesions and/or those of the reproductive and nervous systems, as applicable; written communication (e.g., journal publications or lab reports)
Clinical Pathology Discipline Leader	Establish guidelines and procedures for clinical pathology; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on clinical pathology techniques and evaluations	Subject matter expert	Not required	Doctorate/3 years of experience or equivalent in the biological sciences; D.V.M. and board certification (ASCP) is preferred	Experience in rodent clinical pathology assays, including hematology, clinical chemistry, urinalysis, and hormone assays
Subject Matter Experts: Inhalation Toxicology, DART, Neurobehavioral, Immunotoxicology, Cardiotoxicology, Others as Applicable	Establish discipline-specific scientific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on studies or evaluations involving the specific discipline	Subject matter expert	Not required	Doctorate/3 years of experience in the biological/physical sciences or equivalent; board certification (DABT) is preferred	Experience in the conduct of discipline-specific in vivo rodent toxicological studies; written communication (e.g., journal publications or lab reports)
Subject Matter Experts: Laboratory Animal Veterinarian, Health and Safety Officer, Quality Assurance Officer, Inhalation Exposure, Others as Applicable	For studies conducted at a testing facility other than that of the prime contractor, establish discipline-specific guidelines and procedures; train staff; supervise, technically direct, and/or consult with appropriate professional and technical staff on studies or evaluations involving the specific discipline	Subject matter expert	Not required	Consistent with that described above for the given subject matter	Consistent with that described above for the given subject matter

ACLAM = American College of Laboratory Animal Medicine; AVMA = American Veterinary Medical Association; DACVP = Diplomate of the American College of Veterinary Pathologists; DABT = Diplomate of the American Board of Toxicology; FDA GLP = Food and Drug Administration Good Laboratory Practice; QA = quality assurance.
[a]See text for discussion of key personnel, critical staff, and subject matter experts.

Table 1-2. Overview of Responsibilities for Professional/Technical Support Staff

Professional/Technical Support Staff[a]	Responsibility[b]
Animal Care/Toxicology	Provide animal care/husbandry; administer test articles to rodents (including pregnant dams, neonates/pups, juvenile, and adult animals as required) via required route(s) of exposure; collect in-life data (e.g., body weights, clinical observations, food/water consumption, reproductive evaluations, neurobehavioral evaluations)
Inhalation Exposure	Design, fabricate, develop, and qualify inhalation generation, monitoring, and exposure systems and operate the system during the study
Dose Formulation and Analytical Chemistry	Perform dose formulation, test article identity/purity, and dose formulation analysis (test atmospheres for inhalation studies)
Necropsy and Histology	Conduct dissection and examination of rodents. Specific evaluations will depend on the design of the study and may include reproductive and nervous system examinations; fetal examinations (external, visceral, and skeletal); and assessments of abnormalities/gross lesions; required to be ASCP-registered (HT or MT) technologist to supervise the histology operations
Clinical Pathology	Perform required clinical pathology evaluations
Electronic Data Management (Data Coordinator)	Perform electronic data management activities involving data protocol preparation and data collection, management, reporting, and archiving
Data Management	Perform data management activities, including electronic data capture and archiving aspects
Quality Control	Perform activities to ensure that all information generated by the study conduct staff is accurate, consistent, and complete
Quality Assurance	Perform audits and inspections of study activities

ASCP = American Society for Clinical Pathology; HT = Histotechnician; MT = Medical Technologist.
[a]Professional/technical support staff are not considered key/critical, do not require sponsor approval/notification for reassignment, and are not required to be employed by the contractor.
[b]All technical staff shall have education and training that is appropriate for their responsibilities as deemed by the contractor.

1.1. Peer Review

The Division of Translational Toxicology (DTT) conducted a peer review of chapters 1, 2, 3, 4, 11, and 12 within the draft *Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences* by letter in February 2022 by the expert listed below. Reviewer selection and document review followed established DTT practices. The reviewer was charged to:

1. Peer review the following chapters within the draft Specifications for the Conduct of Toxicity Studies by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences.
    - Chapter 1: General Personnel Requirements
    - Chapter 2: Facilities
    - Chapter 3: Health and Safety
    - Chapter 4: Quality Program
    - Chapter 11: Data Collection and Submission

- Chapter 12: Report Formats and Guidance

2. Comment on the completeness of each chapter.

DTT carefully considered reviewer comments in finalizing this document.

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