

Chemistry Specifications: Section 3. Health and Safety Minimum Requirements

Chemistry Specifications for Chemistry Services Contractors

National Toxicology Program

Health and Safety

September 12, 2013

3.1 Administrative Controls

1. Definitions

1. Throughout this document, the term “Specified Material” refers to a chemical, test article, positive control, or chemical sample, which is a known, or suspect human or animal carcinogen.
2. NOTE: All NTP test articles are to be treated as suspect human carcinogens until demonstrated otherwise.

2. Regulations and Guidelines

1. The NTP and/or its representatives may inspect, photograph, sample and monitor the laboratory and associated facilities used for its studies at any time to ensure that NTP minimum requirements and applicable regulations and guidelines (described below) are being followed. Any deviations to these requirements shall be approved by the NTP.
2. All work shall conform to applicable local, state, and federal statutes in effect at the time of award including the following federal regulations and updates:
 1. Occupational Safety and Health Administration (OSHA)
 1. Standards for General Industry, 29 CFR 1910
 2. Hazard Communication, 29 CFR 1910.1200
 3. Respiratory Protection, 29 CFR 1910.134
 4. Occupational Exposure to Hazardous Chemicals in Laboratories, 29 CFR 1910.1450
 5. Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030
 6. Formaldehyde, 29 CFR 1910.1048 (applicable to the use of formaldehyde in histology, pathology, and anatomy laboratories.
 2. Department of Justice (DOJ)
 1. Americans for Disability Act, Accessibility, Design Guidelines, 28 CFR, Title III, Part 36.
 3. Environmental Protection Agency (EPA)
 1. Clean Air Act, 40 CFR 50-80
 2. Clean Water Act, 40 CFR 100-140 and 400-470

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3. Resource Conservation and Recovery Act (RCRA) 40 CFR 240-271
4. Comprehensive Environmental Response, Compensation and Liability Act (CERCLA, Superfund, SARA) 40 CFR 300.
4. Department of Transportation (DOT)
 1. General Information, Regulations, and Definitions, 49 CFR 171
 2. Hazardous Material Table, Special Provisions, Hazardous Materials Communication Requirements and Emergency Response Information Requirements, 49 CFR 172
 3. Shippers, General Requirements for Shipments and Packaging, 49 CFR 173
 4. Carriage by Public Highway, 49 CFR 177
5. Nuclear Regulatory Commission (NRC)
 1. Standards for Protection against Radiation, 10 CFR 20
 2. Notices, Instruction, and Reports to Workers; Inspections, 10 CFR 19
 3. Recommendations described in the most recent version of the NIH Radiation Safety Guide
6. Drug Enforcement Agency (DEA)
 1. Federal Requirements for Controlled Substance, 21 CFR 1300
3. For contract work involving infectious agents, the Centers for Disease Control Guidelines, Biosafety in Microbiological and Biomedical Laboratories (HHS Publication No. (NIH) 88-8395, 1988) and the NIH Guidelines for Research Involving Recombinant DNA Molecules (Federal Register, Vol. 51, 1986, and updates) shall be followed.
4. Where not superseded by this document, the American National Standard for Laboratory Ventilation, Z 9.5, published by the American National Standards Institute (ANSI) shall be followed.
5. Other consensus standards and publications may include the current edition of the Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices published by the American Conference of Governmental Industrial Hygienists (ACGIH), Criteria Documents for various substances and the Recommended Exposure

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Limits published by the National Institute for Occupational Safety and Health (NIOSH), and the Workplace Environmental Exposure Levels (WEEL) published by the American Industrial Hygiene Association. Where there may be conflict in the acceptable exposure levels as compared to the OSHA Permissible Exposure Limit, the most stringent standard shall be used for worker's protection.

3. Health and Safety Officer/Chemical Hygiene Officer

1. A qualified Health and Safety (HSO) Officer or Chemical Hygiene Officer (CHO) shall be designated to monitor worker health and safety conditions during all phases of the work. The HSO or CHO shall be a full-time employee of the laboratory. The HSO or CHO shall be responsible to someone other than the Principal Investigator (PI) and the PI's subordinates, and shall have the authority to bring unsafe conditions to the attention of higher management. The HSO or CHO may have other responsibilities within the Contractor's organization; however, the amount of time devoted explicitly to health and safety shall be commensurate with the scale of the Contractor's operations.
2. The following qualifications for the HSO or CHO are used as evaluation factors:
 1. Bachelor's degree, in industrial hygiene, chemistry, biology, safety engineering, or a closely related science or engineering field.
 2. At least 2 years experience (part-time) in occupational health and safety along with completion of courses in general occupational health and hazard control indicating the acquisition of successively greater levels of knowledge of chemical health and safety. This experience shall have taken place within the last four years. Training shall have been completed within the last 18 months, and shall be refreshed with additional training at an interval not exceeding 18 months. A master's degree in industrial hygiene, safety engineering or a bachelor's degree in industrial hygiene with one year of experience, is an acceptable substitute for this experience requirement.
 3. Documented experience in working with the requirements of local, state, and federal statutes relating to occupational health and safety, the OSHA Laboratory Standard and Hazard Communication Standard, environmental protection, and chemical and biological monitoring.

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4. Ability to deal effectively with the scientific and managerial staffs in responsibly implementing the health and safety program (including the identification of problem areas and the execution of corrective actions required).
3. All Health and Safety Officer appointments are subject to review and approval by NTP.
4. *Health and Safety Plan (Health and Safety Chemical Hygiene Plan)*
 1. The scope of each Health and Safety Plan shall address the organization's health and safety policies, as well as potential chemical, physical, biological and ergonomic hazards (e.g., acquisition of study materials, storage, and handling through ultimate disposal of contaminated wastes).
 1. No contract laboratory shall participate in studies without a Health and Safety Plan that has been approved by the NTP. An updated Plan shall be submitted every 2 years to the NTP for review. In addition, the NTP shall be informed of any updates to the Plan during the course of the contract. If approval of the Plan is not granted at the time of award, the laboratory must submit a revised Plan for review within 30 days of the receipt of award notification. Revisions to the Plan shall be clearly indicated to facilitate reviewer approval.
 2. For all contract laboratories, a Chemical Hygiene Plan as required under the OSHA "Laboratory Standard" may be used in place of a Health and Safety Plan provided it meets or exceeds ALL of the requirements outlined in this document.
2. *Health and Safety Plan Content*
 1. Written Policies. In addition to the SOPs outlined below, the Health and Safety Plan shall address (but not be limited to):
 1. Health and safety responsibilities, policies and organization
 2. Record keeping and archiving
 3. Initial and periodic employee training
 4. Engineering controls
 5. Personal and environmental monitoring
 6. Medical surveillance and biological monitoring
 7. Respiratory protection program

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8. Personal protective clothing and equipment
 9. General housekeeping
 10. Eating and smoking policies and areas
 11. Precautionary signs and labels
 12. Chemical and biological storage
 13. Fire protection and prevention
 14. Emergency and evacuation contingencies
 15. Locations (with schematic diagrams) of fire control equipment, and plumbed eyewash stations and emergency showers
 16. Laboratory safety inspection
 17. Waste management and disposal
 18. Other pertinent personnel, operational, and administrative practices, and engineering controls necessary for the containment and safe handling of chemical, physical, biological, and radiological hazards
 19. Entry and exit to restricted areas
 20. Visitors
3. *Archival Material*
1. If a contract requirement specifies information is required to be archived, the Health and Safety Plan shall include provisions for placing annually, based on the government fiscal year, in a permanent health and safety data archive, the following information (medical and biological monitoring records are to be retained by the Contractor, or their subcontracted physician or medical group according to OSHA regulations):
 1. Accident and incident reports
 2. Air sampling results
 3. Copies of safety information documents
 4. Copies of the Health and Safety Plan
 5. Log and results of ventilation system performance and maintenance
 6. Name of employee (with title or function)

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7. Confidential records¹
 1. Medical surveillance records
 2. Biological monitoring of laboratory personnel
8. OSHA site visit, inspection, action, complaint reports and resolutions
9. Respirator fit testing program
10. Signed statements from project personnel indicating that they have read and understood all SOPs pertinent to their duties and to the Contractor's Health and Safety Plan.
11. Site and program review reports, attention items, and responses
12. Waste disposal records/incinerator specification.
13. All health and safety archive material is subject to the review by the NTP.

5. Standard Operating Procedures

The laboratory shall be required to have written Standard Operating Procedures (SOPs) that have been reviewed and approved by NTP for at least the following activities:

1. Visitors access to test areas
2. Employee training
3. Medical surveillance and biological monitoring
4. Respiratory protection, mask-fit, cleaning/maintenance, and inspection
5. Eye protection
6. Personal protective clothing and equipment
7. General housekeeping practices
8. Ventilation system maintenance
9. Storage, receipt, transport, and shipping of study materials
10. Hazardous material handling (e.g., in analytical chemistry labs)

¹ The Contractor shall maintain these data chronologically in a limited access archival file.

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11. Dose preparation (if applicable)
 12. Entry and exit from the limited access areas (including traffic patterns of the chemical handling and dose prep facility(ies) and animal handling and testing room) (if applicable)
 13. Spill clean-up, accident, emergency response and evacuation (including natural disasters) and fires/explosions
 14. Use of radio-labeled material, infectious agents, and/or controlled substances (if applicable)
 15. Waste management and disposal
6. Exposure Evaluation and Control
1. *Permissible Exposure Limits/OSHA-Regulated Substances*
 1. All laboratories shall ensure that employees' exposures to hazardous substances do not exceed the permissible exposure limits (PELs) specified by OSHA in 29 CFR 1910, subpart Z. In addition, initial monitoring of employees' exposure to any substance regulated by a standard (29 CFR 1910.1001-1101) that requires monitoring shall be conducted if there is reason to believe that exposure levels for that substance routinely exceed the action level (or in the absence of an action level, the PEL). If this initial monitoring reveals that an employees' exposure exceeds the action level or the PEL, the exposure monitoring provisions of the relevant standard shall be complied with.
 2. If a PEL has not yet been established for a study material, alternative acceptable exposure standards (e.g., TLV[®], REL, WEEL) shall be used (Refer to Section F.I.1, above). In situations where there is no known exposure standard for a proposed study material, the offeror shall derive a suitable interim exposure standard based on current toxicology and industrial hygiene literature.
 2. Specified Material Monitoring for Large-scale Studies²
 1. Exposure monitoring shall be routinely conducted when a Specified Material has an established exposure standard such as the PEL, TLV[®], REL, or WEEL of 10 ppm or less, or 0.1 mg/m³ or less. This exposure

² Large scale refers to laboratories performing experiments with a total of 100 animals or more, and/or a dose administration duration > 10 days.

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monitoring shall be performed at least once during initial dose preparation, once during initial dose administration, and at the midpoint of the study. Where there is no known exposure standard for a proposed study material, the contractor shall perform exposure monitoring at the same frequency stated above. Determination of exposure and adoption of controls shall be based on a pre-determined interim exposure standard.

2. Exposure sampling shall be performed where both Specified Material and controls are handled.

7. Occupational Medical Surveillance

1. Medical examinations for personnel who shall be working with study materials or animals shall be performed at the time personnel are assigned to the program, before they are exposed to potentially hazardous agents.
2. Follow-up medical examinations shall be performed every 12–18 months and upon termination of an individual's participation in the project.
3. The scope of the medical examination shall be specified in the laboratory's Health and Safety Plan. Persons who are required to wear negative pressure respirators must obtain written medical clearance from an occupational health service provider (e.g., an occupational medicine physician, a physician assistant, or nurse practitioner who is supervised by the physician) for use of this equipment.

8. Injury and Incident Reports

1. A record shall be kept of any incidents and illnesses resulting in minor or major personal injury (including animal bites), and/or probable personnel exposure to hazardous agents. These records shall include a full description of the incident, the agent involved, the medical attention required, any remedial actions taken, and planned follow-up to minimize the likelihood or eliminate the potential for reoccurrence (if pertinent). Copies of such incident reports shall be forwarded to NTP.
2. The COR shall be notified IMMEDIATELY if a serious (as defined by OSHA) accident or incident occurs.
3. All occupational injuries and illnesses shall be recorded and reported according to the OSHA recording system.

9. Monthly Status Report (MSR)

The Contractor's MSR shall include a health and safety section that shall be submitted each time it is prepared and sent to the NTP for review and approval. The contents and delivery schedule of the MSR health and safety section shall be as required by Section 4. Reporting Requirements.

3.2. Specified Materials Handling and Safety Policies

1. Receipt/Handling/Storage

1. A log shall be maintained that shall include the date of Specified Material receipt and a continuous balance of the remaining amount of material.
2. Weighing of the Specified Material and/or positive control shall be done using the smallest quantity needed. An analytical balance shall be used whenever possible to preclude the need for handling large amounts of material. This balance shall be placed at all times in an effective laboratory hood or a vented enclosure exhausted to the outside (Part 3.3.3.3). Protocols shall be designed to use the minimum possible quantities of Specified Materials in preparing plates, cultures, or dilutions.
3. A non-breakable, secured secondary container shall be used for transfer of any Specified Material and/or positive control.
4. Volatile Specified Materials shall be handled properly (e.g., keeping lids on container when not in use, segregating from unintended contact with heat or high pressure, etc.) and stored in an enclosure directly vented to the outside. All other Specified Materials shall be stored in a secured, designated storage area(s). However, flammable liquids must be stored in a non-vented flammable liquid storage cabinet (Part 3.5.1.1.3).

2. Hazard Communication

1. Training

Personnel who handle (receive, store, weigh, dilute, transport, package, or administer) hazardous agents shall be provided with written material and trained on the associated hazards of these agents including the contents of the Material Safety Data Sheet (MSDS). This training shall be conducted by the HSO or a program approved by the HSO and shall be properly documented. Training shall include the recommendations for handling carcinogens found in the NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication 81-2385, May, 1981. In

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addition, training in accordance with the requirements of applicable regulations shall be conducted.

2. *Labeling*

Warning signs and labels shall be used wherever Specified Materials are used or stored (e.g., on primary and secondary containers, affixed to entrances to work areas, refrigerators, and on containers holding hazardous waste). These signs and labels shall be conspicuous (especially for containers to minimize handling) and shall indicate the presence of suspected carcinogenic, mutagenic, and other hazards, as required by OSHA, or as recommended by NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication 81-2385, May, 1981.

3. *Health and Safety Documents*

1. The contractor must have available for each study agent and positive control health and safety documentation that includes, but is not limited to, the supplier's MSDS³, which includes information on the material's hazards, properties and appropriate control measures. All employees handling the study material and/or positive control must be trained regarding the contents of the agent-specific health and safety data document.
2. MSDS shall be accessible at all times at designated locations known by the employees.

3.3. *Engineering Controls*

1. *General Facility Requirements*

Safety showers and eyewash stations shall be located throughout the facility as required by local, state, and federal regulations and must be located in close proximity to where potentially hazardous chemicals are stored or used. Only plumbed eyewashes are permitted.

³ If a Specified Material is produced for a user outside of the Contractor's laboratory, then the Contractor is required to develop an MSDS.

2. Isolation and Access Restriction

1. *General Requirements for Access Restriction*

1. An isolated, posted, restricted access laboratory (or laboratories) separate from other laboratory facilities shall be designated for unpacking, storing, weighing, and diluting of Specified Materials and where necropsy, tissue trimming, and tissue processing are performed.
2. Administration of Specified Materials shall be performed in a limited access area with its air supply under negative pressure with respect to connecting laboratories and hallways. This shall be a separate laboratory from the area described above for areas dedicated to unpacking, storing, weighing, and diluting.
 1. Each lab shall have a room inspection program providing monthly checks of the airflow directionality. Relative pressures of laboratory areas shall be checked monthly with smoke tubes to verify that air flows from relatively clean to relatively dirty areas. Monthly inspections shall be documented.
 2. A record shall be kept of all personnel entering/exiting any limited access area(s).

2. *Requirements for Barrier Systems*

1. The neat chemical handling and dose preparation area(s) shall be isolated from general traffic. This may be accomplished by locating the neat chemical handling and dose preparation area(s) within the animal facility limited access barrier system, or by establishing a separate limited access area(s) for neat chemical handling and dose preparation. If the latter approach is used, all areas into which laboratory workers may bring used protective equipment (including gloves, shoes, head covers, and clothing), respirators, and/or containers of dosed feed or water shall be behind the barrier. Also, any hallways used by workers for reaching the shower facility shall be considered to be behind the barrier (e.g., limited access area).
2. Personnel who enter the neat chemical handling and dose preparation area(s), or an area requiring a complete set of clean protective clothing and equipment (e.g., a disposable laboratory suit, safety goggles, disposable gloves (with permeation-resistant properties specific to the Specified Material), disposable boots, disposable shoe covers or

sneakers or rubber boots, and disposable head covering), must shower out prior to leaving the barrier facility at the end of the day.

3. Within the shower facility, the "clean" and "dirty" sides must be physically separated by the shower or by another physical barrier. The facility design and procedures shall be arranged to require showering before entering the clean side and to prevent returning to the dirty side after showering (e.g., to store or retrieve items such as shoes, towels, respirators, etc.).
4. Each laboratory shall have a room inspection program providing monthly checks and documentation of the air flow directionality. Relative pressures of laboratory areas shall be checked monthly with smoke tubes to verify that air flows from relatively clean to relatively dirty areas.

3. *Facility Design for Barrier Systems*

1. Air exhausted from neat chemical handling and dose preparation area(s) involving the particulate form of the test materials shall be passed through HEPA filters. If volatile chemicals are handled, charcoal filters shall also be used. These filtration systems shall be periodically monitored and maintained and personnel performing maintenance shall wear the protective clothing described for neat Specified Material handling. (Part 3.4.1.1).
2. The relative location of external air intakes and exhausts for both local and general ventilation systems must be arranged to minimize the risk of re-entrainment of exhaust air. Documentation (e.g., schematic diagram) shall be provided to NTP indicating the location of intakes and exhausts, stack height, discharge velocities, as well as the direction of prevailing winds. No weather caps or other obstructions shall be in the path of vertical discharge.
3. Within the barrier facility, walls, floors, and ceilings shall be sealed around all incoming and outgoing pipes, conduits, and other utilities to prevent release of contaminated material to surrounding areas. Animal rooms and dose preparation rooms shall be constructed of wall, floor, and ceiling materials which form chemical-tight surfaces. Animal room doors shall include windows to permit observation of workers within each room.

4. Emergency power generator systems shall be in place and emergency generator maintenance and testing shall be documented.

3. Hoods and Vented Enclosures

Where not superseded by requirements in this section, all work shall conform to the current edition of the Laboratory Ventilation Standard, Z 9.5, published jointly by the American National Standards Institute and the American Industrial Hygiene Association. Effluent exhaust concentrations shall not exceed federal, state, and local air pollution emission requirements.

1. *Hood/Enclosure Operations and Requirements*

1. The following operations shall be performed in a laboratory hood or other enclosure:
 1. All dose preparation operations (e.g., weighing, premix, micro encapsulation, mixing of dosing solutions), as well as diluting, or administering (gavage, skin painting, intraperitoneal injection, inhalation chamber administration) of study materials/positive controls.
 2. Specified material weighing in laboratories (e.g., analytical laboratories)
 3. Transfer/filling of dosed feed containers
 4. Unpacking, analysis, and other handling operations involving Specified Materials or other hazardous agents.
 5. Necropsy, tissue trimming, and tissue processing.
 6. Handling tissues, fluids, and exhaled air collected from animals for evaluation.
 7. Cage dumping
2. Plastic-backed absorbent matting shall be secured inside of any hood wherever the Specified Materials (including dilutions) are being handled. After each working session in the hood, or sooner if there is known contamination, this matting shall be disposed of as hazardous waste.
3. Hoods for Weighing, Diluting, or Administering Specified Materials
 1. Laboratory hoods for diluting and administering Specified Materials (including gavage, skin painting, intra-peritoneal injection, and dosed feed hoods) shall provide sufficient contaminant and

containment capture velocities (an average air flow velocity of 100 ± 20 fpm at the operating sash height with no individual point less than 80 linear feet per minute or > 120 linear feet per minute unless it can be demonstrated by testing {e.g., yearly use of smoke candles} that values > 120 fpm provide adequate capture and do not cause turbulence). In addition, face velocities of balance enclosures shall be at least 50 fpm.

2. Safety cabinets used for dilution or administration of toxic chemicals shall recirculate no more than 30% of their air.

4. Exhausted Enclosures/Hoods for Necropsy, Tissue Trimming, and Manual Tissue Processing

An effective exhausted enclosure or hood for necropsy, tissue trimming, and manual tissue processing, as well as for all handling operations involving tissues, fluids and exhaled air collected from animals considered to be contaminated with a Specified Material shall provide capture velocities of 80 ± 10 fpm (with no individual point < 70 fpm or > 90 fpm unless it can be demonstrated by testing (e.g., yearly use of smoke candles) that values > 90 fpm provide adequate capture and do not cause turbulence).

2. *Hood/Enclosure Venting*

1. Hoods and glove boxes used for weighing, diluting, or administering Specified Materials shall be exhausted to the outside.
2. Effluent exhaust vapor from sample oxidizers and/or analytical instruments (e.g., gas chromatograph, atomic absorption spectrophotometer) shall be vented to the outside.
3. Motors for hoods and enclosures exhausted to the outside shall be mounted outside the building such that all ductwork shall be under negative pressure.
4. Re-circulation of air from local exhaust systems into occupied spaces shall not be permitted. The only exception to this shall be for dosed feed container-filling hoods, cage dumping hoods, or vented enclosures for studies involving non-volatile, solid Specified Materials. If re-circulation is desired in this case, the air discharged from hoods or vented enclosures must be equipped with HEPA filtration to clean air prior to its discharge to the study room. The HEPA filter shall be disposed of as hazardous waste (see Section 3.8).

3. *Hood/Enclosure Monitoring*

1. Exhaust enclosures shall be smoke tested using smoke tubes to demonstrate no leakage of smoke out of the enclosure during normal operating procedures.
2. All ventilation systems shall be routinely monitored.
3. The sash height at which the face velocity has been measured shall be marked on each hood along with the date of the last measurement, the measured flow, and name of the person performing the monitoring.
4. The Health and Safety Officer or Chemical Hygiene Officer shall maintain records of ventilation system checks. The records shall indicate for each hood, room, and area, at a minimum, when air was tested, what was found, who conducted the test, and what equipment was used.

3.4. *Personal Protection Equipment Selection*

1. *Selection of Personal Protection Equipment*

1. *Operations Involving Handling of the Neat Specified Material and in Animal Rooms.*

1. Where the neat Specified Material is stored, weighed in dose formulation rooms and in animal study rooms or areas into which personnel directly exit when leaving animal study rooms (e.g., dirty side of the barrier), the following minimum personal protective clothing shall be worn at all times:
 1. Disposable full-body Tyvek suits and disposable head covering, unless the Tyvek suit includes a hood, are required in neat chemical handling areas; dose preparation and administration areas; animal study rooms; and areas into which personnel directly exit when leaving animal study rooms.
 2. When exposure to a neat Specified Material is unlikely, disposable laboratory coats, or disposable Tyvek™ (or equivalent) sleeves disposed of after each use, if a non-disposable laboratory coat is used (any laboratory coat is to be disposed of immediately if there is known chemical contact) and disposable head covering.
3. Gloves

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If chemical-specific gloves cannot be identified, two pairs of dissimilar, disposable gloves (e.g., N-Dexor equivalent, PVC, latex, natural rubber) shall be used. Both pairs shall be changed after any known chemical contact and/or after every 2 hours of use.

4. Respirator

Appropriate NIOSH-approved respirators shall be worn by personnel working where the neat Specified Material is stored, weighed, and diluted and in animal study rooms or areas into which personnel directly exit when leaving animal study rooms (e.g., dirty side of the barrier).

5. Eye Protection

Splash-proof safety glasses, goggles, or other eye protection specified by OSHA and ANSI.

6. Footwear

Disposable shoe covers, disposable boots, or rubber boots.

2. *Operations Not Involving Neat Specified Materials*

1. For laboratory operations not involving the handling of neat Specified Materials (e.g., chemical analysis, histology, tissue trimming, and necropsy [clean side], the following shall be worn:

1. Single pair of disposable gloves
2. Laboratory coat
3. Splash-proof safety glasses, goggles, or other eye protection specified by OSHA and ANSI

2. Respiratory Protection

1. Where specific engineering controls (e.g., vented enclosure for Specified Materials weighing) have been demonstrated to be effective in controlling exposure levels, the need for respiratory protection shall be determined by the Health and Safety Officer.
2. Suitable, NIOSH-approved, task-specific respirators shall be selected by the Health and Safety Officer in accordance with OSHA regulations and NIOSH Respirator Decision Logic recommendations. Where air-purifying respirators (APR) are used (e.g., with gas/vapor and particulate combination cartridges), written provisions shall describe when cartridges are to be changed and the logic used to make this determination. The date

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and time of installation shall be marked on all cartridges. Personnel who are required to wear APR shall be medically cleared, trained, and mask-fitted before they are allowed to wear the respirator.

3. A respirator program that meets the requirements of OSHA 29 CFR 1910.134 shall be implemented for routine and emergency use of respirators.
 4. Any respirator cartridge used during a cleanup of spilled chemical shall be disposed of as hazardous waste.
3. Usage, Storage, and Disposal Practices
1. All protective equipment used in a particular laboratory shall be stored in accessible and convenient locations as dictated by the barrier design or procedures.
 2. Disposable protective clothing shall not be worn out of the laboratory/test work area where neat chemical is handled.
 3. Work clothing shall be removed upon exit from the laboratory on a daily basis.
 4. Previously used disposable clothing shall not be reused, and shall not be worn in common areas such as hallways and offices.
 5. Disposable items shall be discarded as hazardous waste after each use. In addition, any street clothing contaminated with Specified Material (e.g., by a spill) shall be discarded as laboratory contaminated waste. Any street shoes contaminated with a Specified Material shall also be disposed of in the same manner.
 6. Non-disposable items are to be stored in covered containers until washed. If washing is done by laboratory personnel, they shall wear gloves and disposable suits while handling contaminated items. If washing is performed by an outside service, they shall be notified in writing that they are handling items with potential contamination.

3.5. Fire Safety

NOTE: Fire safety requirements for Inhalation studies are described in Part 3.9. The facility and operations shall comply with applicable federal, state and local fire and building codes.

1. Storage and Handling

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1. Flammable liquids shall be stored and handled in a manner that reduces the risk of fire and/or explosion. This includes the following:
 1. All non-working quantities of flammable liquids shall be stored in storage cabinets approved by Underwriters Laboratories or Factory Mutual, or in a designated flammable liquids storage room with suitable fire protection, ventilation, spill containment trays, and with equipment meeting the requirements of OSHA. In either storage arrangement, the flammable liquids shall be segregated from other hazardous materials such as acids, bases, oxidizers, etc.
 2. Flammable storage cabinets shall not be vented unless required by a chemical-specific OSHA regulation or by local authorities. Metal bung caps shall be used in place of flash arrestor screens. If it is necessary that venting be provided, the following shall be adhered to: (1) Remove both metal bungs and replace with flash arrestor screens. The top opening shall serve as the fresh air inlet. (2) Connect the bottom opening to an exhaust fan by a substantial metal tubing having an inside diameter no smaller than the vent. The tubing shall be rigid steel. (3) Ensure that the fan has a non-sparking fan blade and non-sparking shroud. It shall exhaust directly to the outside where possible. (4) The total run of exhaust duct shall not exceed 25 feet.
 3. Class I flammable liquids shall not be stored in conventional refrigerators/freezers. If flammable liquids must be kept at low temperatures, they shall be stored in Underwriters Laboratory (UL) listed/Factory Mutual (FM) Global approved refrigerators/freezers designed for flammable storage. In a potentially flammable or explosive atmospheric environment, only those explosion-proof refrigerators/freezers listed for Class I, Division 1, Group C and D, and listed by UL as a "Special Purpose Refrigerator and/or Freezer" shall be used. All explosion-proof refrigerators shall be labeled as such.
 4. Whenever flammable liquids are stored or handled, ignition sources shall be eliminated. This includes the prohibition of smoking.
2. Flammable liquid transfer shall be done in the designated storage room or over a tray within an effective laboratory hood. In the former location, all transfer drums shall be grounded and bonded and shall be equipped with pressure relief devices and dead man valves.

3. Safety cans shall be used when handling small (e.g., no more than 2 gallons) quantities of flammable liquids, unless chemical purity requirements state otherwise (e.g., distilled-in-glass grade, etc.).

2. Fire Safety Equipment

1. *Fire Extinguishers*

Fire extinguishers shall be conspicuously located where they shall be readily accessible and immediately available in the event of fire as required by local, state, and federal regulations. Placement of portable fire extinguishers shall conform to OSHA 1910.157. The specific type and size of extinguisher shall be selected with consideration for the hazards to be protected and the physical strength of the personnel who might use the extinguishers. For the majority of laboratory applications, water and aqueous film forming foam (AFFF) extinguishers shall have a capacity of 2-1/2 gallons. Dry chemical, carbon dioxide, and foam extinguishes shall be 20- to 30-pound capacity.

2. *Safety Showers*

Safety showers shall be located in the immediate vicinity of every laboratory where flammable liquids are stored/used. Fire blankets may be used if available.

3. Training

All personnel shall receive training in fire safety. Course material shall include hazard awareness, proper techniques for the handling and storage of flammable liquids, and a briefing on the alarm system and emergency evacuation preplanning. In addition, "hands-on" training for appropriate personnel on fire extinguishers is encouraged.

3.6. **Emergency Procedures**

1. The written set of general safety policies (SOPs) shall include actions to be taken in case of fire and/or explosion. They shall address personnel assignments, evacuation routes, and notification procedures. The National Fire Protection Association Life Safety Code, Number 101, and existing manual pull-box locations shall be considered when establishing means of egress.
2. A written set of emergency/evacuation procedures to be followed by all project personnel in the event of a spill or leak involving a Specified Material shall be developed and posted in each laboratory. Personnel shall be

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instructed to call for appropriate help (e.g., in-house emergency group or poison control center) in case of an emergency. This plan shall address the storage, use and maintenance of emergency protective equipment.

3. The location and phone number of the nearest poison control center and any other emergency phone numbers shall be prominently posted in each laboratory.
4. Emergency protective equipment shall not be stored in the laboratory where Specified Materials are stored and handled.

3.7. Shipment

1. Shipment of Specified Materials

The following practices shall be adhered to concerning the shipment of Specified Materials:

1. Packaging

1. Specified Materials and formulations shall be packaged so as to minimize the possibility of exposure to personnel involved in the packaging, transportation, and receipt of these chemicals. The requirements shall be consistent with the DOT regulations (or International Air Transport Association (IATA) regulation for contractors outside the USA) as outlined in 49 CFR, parts 100 to 199.
2. Specified Materials shall be shipped in primary containers compatible with the physical and chemical properties of the materials to prevent contamination of the study material. Each primary container must be securely sealed to prevent leakage during transport. After being sealed, the exteriors of each primary container must be decontaminated and labeled with all pertinent information, including species and strain (when applicable), all identifying sample codes (contractor- or source-supplied), amount, date, and source (if the material is not the original source material, the original source must be included with the current source information). Specified Materials that are gases or liquefied gases in cylinders shall be shipped without additional packing and according to appropriate transportation procedures.
3. All primary containers shall be sealed in double plastic bags to prevent leakage and exposure if broken, surrounded by absorbent material and placed in secondary containers. Larger amounts of liquids may be shipped in 5-gallon metal drums that are individually packaged and

that meet all DOT regulations. These 5-gallon drums must be over-packed in larger drums with absorbent material, securely sealed, and fully labeled. All over-packed drums shall be fully filled, securely sealed, and completely labeled on the outside.

4. Outside containers shall be free from extraneous and ambiguous labels. Labeling shall include a directional label to indicate the top, appropriate warning labels, e.g., BIOHAZARD, FLAMMABLE, and all required DOT labels and identification. All shipments shall be made in compliance with DOT regulations (or IATA regulations where applicable) and accompanied by a completed Shipper Certification Form for Hazardous Materials. A detailed packaging list shall be placed on the outside of the shipping container identifying each sample by name, amounts shipped, and sample codes of each Specified Material. NTP shall be consulted if the quantity or type of substance to be shipped renders these requirements inappropriate.

2. *Shipping*

Shipments shall conform to all applicable local, state, and federal regulations.

3.8. ***Waste Disposal***

1. All potentially contaminated material (e.g., used personal protective clothing and equipment, absorbent materials for handling test materials, disposable cages, lab ware, filters, respirator cartridges, etc.) shall be incinerated in a manner consistent with federal (EPA) and local regulations, or disposed of in a licensed hazardous waste landfill. Animal carcasses, blood samples, animal tissues, or any other materials that are grossly contaminated with blood, including sharps and syringes, shall be collected and disposed of by incineration. The laboratory shall indicate whether it plans to fulfill this requirement with its own incinerator, or by use of a licensed waste disposal firm. If the laboratory's incinerator is to be used, specifications (e.g., temperatures and residence times), operating procedures, and information on licensing by local regulatory authorities shall be provided to NTP for evaluation. If a contract disposer is to be used, complete information on the firm's licensing and hazardous waste transporter shall be provided.
2. Where data terminals or computers are used in the presence of potentially toxic substances, a protective covering (e.g., plastic wrap) shall be placed over the keyboard when it is in use (as is feasible). After each use, the terminal shall be decontaminated using a protocol-specific solution. Terminals

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must be disconnected from any electrical power sources before decontamination, and care shall be taken to ensure that any solvents used do not damage the plastic parts of the terminal or computer.

3. Vacuum lines, including water aspirators, used when working with a Specified Material and/or positive control shall be protected with an absorbent or liquid trap and a HEPA filter.