# Program Description

# Animal Care and Use Program

# Center for Food Safety and Applied Nutrition Program

# Food and Drug Administration

## 8301 Muirkirk Road

## Laurel, MD 20708

## December 1, 2018

## For

## AAALAC International

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**Appendices**

## Program Description

## Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

### Section 1. Introduction

**A.** State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

The program unit is the Center for Food Safety and Applied Nutrition (hereinafter, "CFSAN" or "the Center"), a part of the U.S. Food and Drug Administration (FDA). The CFSAN animal research program consists of a headquarters facility in the Office of Applied Research and Safety Assessment (OARSA) in the MOD-1 facility in Maryland, an aquaculture facility in the Gulf Coast Seafood Laboratory (GCSL) in Alabama, and a mouse facility in the Moffett Center in Illinois.

**B.** Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

CFSAN is the science-based program unit of FDA responsible for implementing the Federal Food, Drug and Cosmetic Act to assure that food and cosmetic products offered for sale through interstate commerce by domestic and foreign suppliers to the U.S. marketplace are safe and honestly labeled. Commodities are regulated to not contain harmful amounts of natural or man-made adulterants such as toxins, molds, pathogenic microorganisms, industrial chemicals, or toxic metals. The Center also assures the safety of substances that are intentionally added to food (food additives) or that are transferred by contact of packaging material with food. This is done by review of relevant data and approval prior to marketing of food containing such direct or indirect additives. CFSAN is also responsible for cosmetics and has developed a research program to examine the safety of cosmetics products containing nanoparticles. Part of the Center's research and safety testing of regulated commodities is performed using laboratory animals. Among other governances, that part is governed by the Center's Program for Animal Care and Use.

**C.** Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

The CFSAN animal research program has an Office of Laboratory Animal Welfare (OLAW) Assurance (Assurance Number D16-00650 (A4294-01) and uses the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* and *ILAR Guide* for agricultural animals used in biomedical research.

**D.** Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publically available, provide the titles and names; for individuals whose information is not publically available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

The organization chart is appended (Appendix 4). The organization is composed of four program offices that report to the Deputy Center Director for Regulatory Affairs, and two program offices and two research offices that report to the Deputy Center Director for Scientific Operations. The Office of Applied Research and Safety Assessment (OARSA) encompasses Module 1 (MOD-1), the CFSAN

main animal facility and falls under the Deputy Director for Scientific Operations. The Gulf Coast Seafood Laboratory (GCSL) and the Moffett Center, each containing an animal research satellite facility, are in the Office of Food Safety that reports to the Deputy Director for Regulatory Affairs. The Deputy Director for Scientific Operations for CFSAN and the Deputy Director for Regulatory Affairs report directly to the Center Director.

Dr. Susan Mayne, the Center Director and Chief Executive Officer, has designated the person in the position of the Director of the Office of Applied Research and Safety Assessment to serve with full authority and responsibility as the Institutional Official for animal activities at the Center's three facilities, Module 1 (MOD-1), the Gulf Coast Seafood Laboratory (GCSL), and the Moffett Center. The CFSAN Institutional Official, Dr. Mary Torrence, has crosscutting responsibility across all Center lines of management regarding animal care and use. Dr. Mary Torrence, Director of the Office of Applied Research and Safety Assessment (OARSA), has responsibility for managing the CFSAN research activities at MOD-1, CFSAN's main animal facility. Dr. Torrence supervises (b) (5) for the CFSAN animal research program. Apart from the management lines of authority, the Attending Veterinarian has a direct line of communication to the Institutional Official on matters pertaining to animal care and use. Dr. Torrence supervises (b) (5) the CFSAN Research Facility Manager for MOD-1 and the Contracting Officer's Representative (COR) for the Center's contract animal care services at MOD-1. The Animal Husbandry Unit Contract Manager, (b) (5) reports to (b) (5) . (b) (5) the IACUC Chairperson, reports to (b) (5) and (b) (5) but has a direct line of communication to the Institutional Official on matters pertaining to animal care and use. Dr. Marianne Solomotis, Deputy Director of OARSA, is the Responsible Official (RO) for the MOD-1 Select Agent Program and is the Deputy Director of OARSA.

The (b) (5) reports to the (b) (5) in the Center's Office of Food Safety. The Animal Care Coordinator at GCSL, (b) (5) reports to the Director of GCSL and along with another biologist provides animal care. The (b) (5) also reports to the Director. The Director of the Division of Food Processing Science and Technology at the (b) (5) reports to the (b) (5) at the Moffett Center, and is the RO for the select Agent Program. (b) (5) reports to the Process Engineering Branch Chief in the Division of Food Processing Science and Technology and supervises one biologist who provides animal care.

**E.** Identify the key institutional representatives (including, but not limited to, the Institutional (b) (5)
individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

- Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition; Chief Executive Officer
- Steven M. Musser, Ph.D., Deputy Director for Scientific Operations, Center for Food Safety and Applied Nutrition
- Mary Torrence, DVM, Ph.D., DACVPM. Director, Office of Applied Research and Safety Assessment, Institutional Official
- Marianne Solomotis, Ph. D., Deputy Director, OARSA
- (b) (5)
- (b) (5)
- (b) (5) for the Moffett Center
- (b) (5) COR for the Animal Husbandry Contract
- (b) (5) Animal Husbandry Unit Contract Manager IV
- (b) (5) Muirkirk Road Complex
- (b) (5) Office of Management
- (b) (5) Office of Management
- (b) (5) Laboratory, Office of Food Safety
- (b) (5) Moffett Center, Office of Food Safety
- Karl F. Reineke, B.A., Animal Caretaker, Facility Manager, Moffett Center, Office of Food Safety

- (b) (5) Assurance Staff
- (b) (5) , Office of Applied Research and Safety Assessment
- (b) (5) , Clym Environmental Services

**F.** Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The Center's research program is directly relevant to FDA's mission and deals with issues not ordinarily addressed by other research organizations or the regulated industry. The program focuses on public health variables in such fields as microbiology, nutrition, food allergy, and toxicology as acted upon by entities such as food additives, cosmetic ingredients, and chemical, microbial, viral and other contaminants in foods and cosmetics. The program is designed to develop and apply technologies for the detection, identification and risk assessment of contaminants in foods and cosmetics, and to explore the toxicity as well as the nutritional quality of foods.

For foods, risks of adverse health effects arising from small but persistent amounts of toxicologically potent substances, such as carcinogens, mutagens, teratogens, and natural toxins found in the U.S. diet, are investigated. Research involves identifying hazardous substances, assessing the nature of adverse effects, and defining dose-effect relationships. The pharmacokinetics of hazardous substances in biological models are studied, emphasizing mechanistic effects. Subtle behavioral effects of food substances, the impact of unhealthy dietary habits, adverse effects of nutrients consumed in excess of requirements, and bioavailability of nutrients in new food products are examined.

Nutrition research focuses on substances of regulatory significance in food. Factors affecting the action of these substances on reproduction, growth, and development, and the metabolic fate and interaction of such substances with food additives and other food components in whole animals are studied.
(b) (4) studies are conducted to examine the impact of new foods and food additives on the nutritional quality of the U.S. diet and on public health.

In food microbiology, the role of microbial flora in disease causation and the effects of bacterial toxins on living systems are examined. Research includes methods development for pathogen identifications in foods, identification of virulence factors that play a role in immunologically-mediated diseases, changes in food technology, dietary habits, and microbial populations. Areas of research also include the effects of new processing techniques on the microbiological safety and quality of foods, exploitation of bioengineering techniques to facilitate rapid and precise identification of public health problems of microbial origin and obtaining a level of acuity to regulate new foods and food additives produced through biotechnology. The Center research also focuses on food allergenicity. Studies are being conducted on the components of specific food matrices that are responsible for the allergic response, and on potential mediators of the response. Studies are also being conducted to investigate the role of immune modulators in host defense and inflammatory response to foodborne pathogens.

For cosmetics, (b) (4) studies are performed to assess, following percutaneous absorption, the effects of cosmetic ingredients on other organ

systems. CFSAN has established ex vivo methods and models to assess the skin absorption of chemicals of concern to CFSAN. Methods developed in this area are under consideration by the Organization for Economic and Community Development for adoption as international standards. CFSAN is currently developing an in vitro buccal membrane absorption (IVBMA) model to assess the exposure and hazard of orally absorbed chemicals and constituents of concern to CFSAN.

Studies are conducted at the Gulf Coast Seafood Laboratory with fish and other aquatic food organisms on the isolation, structural elucidation, and characterization of seafood biotoxins from progenitor (e.g., algal) cultures and seafood (finfish and shellfish) vectors. Investigations on microbial and viral hazards and aquaculture drugs found in finfish and shellfish are also conducted.

The Moffett Center conducts collaborative food safety and security research at the National Center for Food Safety and Technology in food processing, food packaging, biotechnology, quality assurance as it relates to the food processing and handling principles, methods, and techniques, and the utilization of new technology instruments and equipment in food processing and packaging. The program also conducts specific FDA regulatory food safety and security research and provides technical expertise and training in food processing and packaging, as requested, to FDA's regulatory and enforcement units and in support of Center and FDA Office of Regulatory Affairs programs. A portion of the research program, that includes the animal program, is registered with the CDC Select Agent Program to work with select agents. This work examines technologies utilized to inactivate toxins that can be naturally occurring or used as microbiological threat agents in food. The Moffett Center program utilizes mice only.

In accord with FDA policy of October 7, 1992, CFSAN conducts regulatory animal tests using official methods (e.g., Association of Official Analytical Chemists), such as the botulinum toxins bioassay, to assess the safety of food and cosmetic products.

There are currently 11 CFSAN scientists designated as Principal Investigators (PI) for (b) (4) studies. There are currently 7 active research and testing protocols using laboratory animals. The Animal Usage Form is appended (Appendix 5).

**G.** Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Funds for the Center's animal research program are derived from an annual FDA budget.

**H.** List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
*Note:* Questions regarding this section should be forwarded to the AAALAC Office.

Not Applicable

**I.** Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

Not Applicable

**J.** Note other relevant background that will assist reviewers of this report.

Not Applicable

## Section 2. Description

### I. Animal Care and Use Program

#### A. Program Management

**1. Program Management Responsibility** [*Guide*, pp. 13-15]

**a. The Institutional Official** [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The IACUC Chairperson and the Attending Veterinarian have direct lines of communication to the Institutional Official (IO). The Chairperson and the Attending Veterinarian schedules meetings with the IO as needed. The IO is also available if issues or needs arise that must be immediately addressed. The Director of OARSA (IO) has regularly scheduled meetings with the Deputy Center Director for Scientific Operations that include discussion on the needs of the Office including those of the animal research program. The IACUC utilizes a secured computer drive for all communications associated with the animal research program, and the IO has access to all documents and communications contained on the drive. The CFSAN IO is responsible for oversight of all research activities that include animal research. The IO can review all animal research and interact with the scientists conducting the studies. In addition, the IO is available to any member of the CFSAN animal research program to discuss the needs of the program.

**b. Role of the Attending Veterinarian** [*Guide*, p. 14]

**i.** Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

**MOD-1**

Animals in the MOD-1 vivarium receive care from (b) (5) . (b) (5) devotes 100% of his time and efforts to support the animal care and use program, split approximately 60% spent on direct veterinary care of animals and 40% on administrative, training and related activities.

Responsibilities of the veterinary staff include providing appropriate methods to prevent, control, diagnose, and treat diseases and injuries of animals. The veterinary staff provides emergency, weekend, and holiday care for animals as a follow-up to timely observations of animals and reporting of abnormal findings by animal care technicians through an established mechanism.

The veterinary staff provides guidance for principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, and euthanasia. The veterinary staff provides training on technical procedures and animal welfare to all individuals involved in animal research. The veterinary staff also provides oversight of animal orders and vendor quality assurance.

**GCSL**

Management of the GCSL aquaculture facility, including the care and use of the aquatic species housed at that site, is the responsibility of the Principal Investigator. In cases of unforeseen problems pertaining to fish health, (b) (5) is available by telephone, and can provide guidance on animal care.

**Moffett Center**

Management of the Moffett Center Mouse Facility, including the care and use of mice housed at that site, is the responsibility of the Principal Investigator. In cases of unforeseen problems pertaining to mice health, the Center has developed an agreement with (b) (5) a veterinarian employed by the Rush University Medical Center who specializes in laboratory animal medicine. (b) (5) provides consultation for all (b) (4) studies. He is available by telephone or can be available in person when necessary, since he is located within 1 hour of the Moffett facility. (b) (5) participates in the semi-annual facility inspections of the Moffett Center when animals are present in the facility.

The (b) (5) for the MOD-1 facility, (b) (5) is the back-up veterinarian if (b) (5) is not available.

**ii.** List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Not Applicable

**c. Interinstitutional Collaborations** [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

Center for Veterinary Medicine (CVM) via Memorandum of Understanding (MOU).

## 2. Personnel Management

**a. Training, Education, and Continuing Educational Opportunities**
Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.
*Note:* Do not include details about the training program, which should be described in the following sections.

**MOD-1**

The Attending Veterinarian is the Principal Investigator for the training protocol used for all live animal training procedures conducted in the MOD-1 facility. Training is provided under this protocol by members of the veterinary staff or research staff approved by the Attending Veterinarian to provide training. The Attending Veterinarian evaluates all trainees and provides a written description of the training provided and an evaluation of the technical competence of each person receiving training. The training program is also under the CFSAN Post Approval Monitoring Program, a written evaluation of training sessions is provided by the post approval monitor to the IACUC for review.

**GCSL and Moffett**

Training at the satellite facilities is conducted by the Principal Investigator(s), the associated veterinary staff, and/or outside consultants. This information is communicated to the IACUC during regularly scheduled meetings of the committee and is included as part of the meeting minutes.

**i. Veterinary and Other Professional Staff** [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

*Note:* Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

(b) (5)

- D.V.M., Araneta University, Manila, Philippines, 1980Continuing education courses in veterinary medicine, laboratory animal science, and animal pain and distress management, AAALAC, National Capitol Area Branch of the American Association of Laboratory Animal Science (NCAB-AALAS), PRIM&R/ARENA, AFIP, OLAW, Scientists Center for Animal Welfare (SCAW), American Veterinary Medical Association (AVMA), United States Department of Agriculture Food safety and Inspection Service (USDA FSIS), FDA Center for Veterinary Medicine (CVM) University of Maryland School of Public Health, NIH, and Charles River Laboratories.
- Thirty-one years of research experience in clinical veterinary medicine and surgery, 10.5 years with FDA.
- •Member of the AVMA and the American Society of Laboratory Animal Practitioners (ASLAP).

(b) (5) **for the Moffett Center**

- D.V.M, University of Illinois, Champaign-Urbana, IL, 1995
- Laboratory Animal Medicine, Postdoctoral Training Program, University of Illinois at Chicago, Chicago, IL, 1998
- Diplomat, American College of Laboratory Animal Medicine, 1999
- 22 years of experience in clinical veterinary medicine, currently Senior Director of Rush University Medical Center, Comparative Research Center in Chicago.

**ii. Animal Care Personnel** [*Guide*, p. 16]

**1)** Indicate the number of animal care personnel.

**MOD-1**

4 Contract Animal Care Personnel

**GCLS**

2 Government Animal Care Personnel

**Moffett Center**

2 Government Animal Care Personnel

**2)** Summarize their training, certification level and type, experience, and continuing education opportunities provided.
*Note*: If preferred, this information may be provided in a Table or additional Appendix.

**MOD-1**
Animal care is provided at the MOD-1 vivarium through a contract with Priority One Services Inc. The essential positions within the animal husbandry contract are outlined below.

(b) (5)
• B.A. in Psychology in 1985 from Inca Garcilazo of Vega University
• AALAS-certified Laboratory Animal Technologist, 1997
• Graduated from the Institute for Laboratory Animal Management (ILAM) in 2001
• Graduated from the Leadership Training Program (LTP) in 2006
• Member of the Laboratory Animal Management Association (LAMA) and the National Capitol Area Branch (NCAB) of AALAS since 1997. Member of Laboratory Animal Welfare Training Exchange (LAWTE) in 2004
• 25 years of experience in laboratory animal science, including 20 years in a supervisory or manager position
• Held positions in seven AAALAC accredited facilities and was an IACUC member in one of the programs
• Has experience with all animal species used in the MOD-1 facility.
• Primary responsibilities include oversight of contract employees at MOD-1, quality control, administrative activities, and interaction with corporate headquarters

• Continuing education includes attendance at annual NCAB/AALAS workshops and seminars
• CFSAN has provided supplemental training on conducting (b) (4) studies, Biosafety training including working on studies conducted at ABSL-3, and the MOD-1 Select Agent Program

(b) (5)
• AALAS certified as Laboratory Animal Technologist, 1999
• Over 15 years supervisory experience including 10 years as a Facility Manager
• Graduated from ILAM 2007
• SA register employee, since 2014
• Responsible for ensuring that animal husbandry and technical duties are performed in accord with established SOP's
• Continuing education includes attendance at annual NCAB/AALAS workshops and seminars.

In addition to the staff described above, the animal husbandry contract personnel includes 1 animal technician, 1 animal caretaker, 1 support person in cage wash, and an administrative assistant. Laundry and custodial services for the animal facility are also provided by Priority One Services, Inc.

The animal technicians and animal caretakers are AALAS certified at the Laboratory Animal Technologist (LAT) and Assistant Laboratory Animal Technician (ALAT). Additionally, they are experienced in supporting ongoing CFSAN research initiatives by providing technical support to include animal identification, dosing, collection of blood, necropsy, and specimen collection.
Under the contract terms, Priority One Services Inc. is responsible for necessary training of contract staff. This is provided by Priority One Services' senior personnel through weekly training sessions that are made available to all staff. The veterinarian and PIs may also participate when live animals are involved. Contractor training includes:

- Animal care and husbandry
- Facility and equipment sanitation
- Cage wash principles and operations
- Animal care and use standards and regulations
- Dose administration
- Specimen collection
- Euthanasia
- Necropsy
- Data collection and record keeping
- AALAS

- Safety
- Standard Operating Procedures

Additionally, training activities that are provided to the animal care staff include AALAS workshops on rodent and rabbit handling/techniques, occupational health and safety topics, blood- borne pathogens, and hazard communication. In addition, the contractor affords the opportunity to the animal care staff to attend the annual seminar of the NCAB/AALAS. Training is also provided to Priority One staff by the PI or the Veterinary Staff for procedures that are unique to a specific protocol. Training records are maintained by Priority One Services Inc. These are reported quarterly and in an annual report that is submitted to the FDA COR to document the employee training provided during the reporting year with a training plan for the forthcoming year.

**GCSL**

The Principal Investigator and study personnel are responsible for the daily observations and well-being of study animals. The Attending Veterinarian is available by telephone, e-mail, or cell phone 24 hours/day, 7 days/week for consultation on problems that may be encountered. The qualifications of the primary animal care personnel for GCSL are described below.

(b) (5)

• B.B.A., Marketing, Texas A&M University, 1988
• M.S., Food Science and Technology, Texas A&M University, 1993
• Ph.D., Food Science and Technology, University of Florida, 2001
• 15 years tenure at FDA and 10 years' experience at GCSL, as a seafood quality and safety researcher. Primary area of research focus has been seafood decomposition. Continuing education through participation in national and international scientific meetings (e.g., Pittcon and International Association for Food Protection) and frequent critical reading of peer reviewed journals (e.g., Journal of Food Protection, Journal of Food Science, and Journal of Aquatic Food Product Technology)

(b) (5)

• A.A., Pre-Professional Science, Anne Arundel Community College, 1972
• B.S., Animal Sciences, University of Maryland, 1992
• 39 years tenure with FDA, 26 years at GCSL, as a laboratory animal science research technician/biologist with experience in domestic, laboratory and aquatic animal care and use
•Continuing education through training (IACUC 101/201), participation in national and international scientific meetings such

as the World Aquaculture Society and the International Conference on Harmful Algae, Annual Meeting of the Alabama Fisheries Association, and the Catfish Farmers of America Annual Convention. Membership in professional organizations such as the American Fisheries Society, NCAB/AALAS, ISSHA, Catfish Farmers of America and the Alabama Fisheries Association. Subscriptions to a peer reviewed journal and both online and print aquaculture newspapers.

**Moffett Center**
The principal investigator and study personnel are responsible for the daily observations and well-being of study animals. The Attending Veterinarian is available by telephone, e-mail, or cell phone 24 hours/day, 7 days/week for consultation on problems that may be encountered. In addition, the consulting veterinarian is available for telephone consultation and/or site visitation on an as- needed basis. The qualifications of the primary animal care personnel for the Moffett Center are described below.

(b) (5)

- Ph.D., Nutrition and Food Science, Utah State University, 1981
- 26 years tenure at Moffett Center, conducting research in the area of *Clostridium botulinum*.
- Publications in archival journals and presentations at professional meetings.

(b) (5)

- B.A., Indiana University, 1994
- 23 years of experience in food safety research at Moffett Center
- Publications in archival journals and presentations at professional meetings

**iii. The Research Team** [*Guide*, pp. 16-17; 115-116; 122; 124]

**1)** Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

**MOD-1, GCSL, and Moffett Center**

All personnel must complete a training and experience form as part of the protocol form that is evaluated by the Veterinary Staff and the IACUC as part of the protocol review. For researchers to be

considered competent on a specific procedure they must have conducted the procedure within the past 3 years on the species being utilized for the study.
Researchers without current training and experience in a specific technique or animal species must obtain training through the CFSAN veterinary staff for studies conducted at the MOD-1 facility. Training is provided at the GCSL and the Moffett Center through the principal investigators and the Animal Care Coordinator or provided through outside consultants. The satellite facilities can also request training from the veterinary staff as needed.

**a)** Briefly describe the content of any required training.

**MOD-1**

Investigators are trained on the traffic patterns for the dual corridor facility and the Personal Protective Equipment (PPE) required for each area of the facility, plus additional PPE required for a specific study is provided by the PI. Training is provided on the specific technical requirements for the study such as handling, restraint, dosing, blood collection, euthanasia and necropsy. The veterinary staff and/or PI also provide information on the pain and distress that may result from the study and the scientific end-points for the study. The veterinary staff also provides training on the *Guide* and the Animal Welfare Act. The IACUC reviews the technical training and experience of all individuals listed on a protocol to determine if training is required prior to initiation of a study. Personnel must have performed the procedures within the past 3 years in the species used for the study, and must have performed these procedures as a researcher in the CFSAN animal research program.

New investigators working with botulinum toxin are provided training by the Principal Investigator and the Safety Office.

**GCSL**

Training to new personnel is provided by the PI and the Animal Care Coordinator. Training includes proper care of aquatic species, PPE required, and the technical procedures required for the specific study.

**Moffett Center**

Training is provided by the Research Animal Resource Center at the University of Wisconsin, Madison. Refresher training is provided to all personnel and will be provided before animals come into the facility. The topics include animal restraint, IP injection, and euthanasia.

**b)** Describe the timing of training requirements relative to the commencement of work.

Training must be completed before a person can conduct animal research. All personnel on a study must demonstrate technical competence for each procedure in each animal species utilized in the study prior to working on an animal study.

**c)** Describe continuing education opportunities offered.

CFSAN has established a resource portal that is available to all principal investigators and CFSAN personnel interested in conducting animal research. The resource portal provides reference material and guidance on developing an animal research protocol, standard operating procedures for (b) (4) studies, Institution policies, and pertinent animal reference materials.

The CFSAN animal research program allocates funding to provide continuing education for investigators.
Investigators in the MOD-1 facility are provided an opportunity to attend the Annual National Capital Area Branch of the American Association for Laboratory Animal Sciences (NCAB AALAS) meeting. CFSAN is Institutional Member of NCAB AALAS which provides opportunities for continuing education. They are also encouraged to attend training sessions provided by the local Animal Welfare Information Center (AWIC) located at the USDA facility in Beltsville, MD. Investigators can also request funding for specific training through the animal research program. The CFSAN animal program is a member of the Scientist Center for Animal Welfare (SCAW), and investigators are provided the opportunity to attend the SCAW Workshops. Applicable webinars provided through AAALAC are also provided to investigators as seminar series and as archived seminars were available. The CFSAN IACUC provides training as needed to the investigators on

topics such as new policies from AWIC and AAALAC, changes to the CFSAN animal research program, and the CFSAN veterinary staff provides both new and refresher training to all investigators involved in animal research. IACUC members have access to the Collaborative Institutional Training Initiative (CITI) Program at the University of Miami that includes training modules for IACUC members as well as modules on responsible animal research and working with various animal species in the research setting.

**2)** Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

The program had one approved surgical protocol that required implantation of telemetry devices into rats. This protocol is completed. This protocol supported studies to assess the effects of active ingredients in dietary supplements on electrocardiogram parameters, heart rate, blood pressure, body temperature, and respiration rate. Personnel performing the surgery and the Attending Veterinarian (AV) received training in the MOD-1 surgical suite from the manufacturer of the telemetry device, Data Sciences International (DSI). Following the initial training, a surgical training protocol was developed and all personnel performing implantation surgery perfected their technique under the supervision of the AV. The AV reported to the IACUC on each training session. Two research personnel are qualified to perform the surgical procedures and provide training on the surgical implantation techniques. The training is conducted on a training protocol under the supervision of the AV. The veterinary staff provided oversight of this training and provided reports to the IACUC. Training was also monitored through the PAM program, and observed by members of the IACUC. The AV in conjunction with the trained research personnel determined personnel qualified for specific surgical procedures.

The surgical protocol is completed and no more surgeries are planned under any surgical protocols.

**3)** Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

**MOD-1**
In the MOD-1 facility, for new and established anesthesia regimens, a veterinarian is present to observe and monitor personnel and animals during the procedure. The veterinarian determines the experience of the Principal Investigator and monitors anesthetic procedures to determine the investigator's level of competence. Supplemental training is provided if necessary. AHU employees provide rodent anesthesia training to new AHU personnel. Anesthesia training on the higher species is provided to AHU personnel by the veterinary staff.

**GCSL**
The only anesthetic agent used at the GCSL is tricaine methanesulfonate (MS-222) administered through water exposure utilizing bronchial absorption. (b) (5) who has extensive experience with fish anesthesia, monitor personnel and animals during procedures that utilize MS-222.

**Moffett Center**
Anesthesia is not utilized in the Moffett Center animal facility.

**4)** Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

All personnel conducting euthanasia within the CFSAN animal research program must have documented training and experience with the specific euthanasia techniques on the species being euthanized.

**MOD-1**
Personnel in the MOD-1 facility without the necessary experience must obtain training through the veterinary staff and be approved by the veterinary staff prior to conducting euthanasia procedures. Euthanasia is monitored through the Post Approval Monitoring program.

**GCSL**

New investigators are trained and approved by the Principal Investigator and/or the Animal Care Coordinator.

**Moffett Center**
Personnel in the Moffett Center facility without the necessary experience must obtain training through the Principal Investigator and the veterinarian. Euthanasia procedures at the Moffett Center are monitored by the Principal Investigator and the Contract Veterinarian.

**b. Occupational Health and Safety of Personnel** [*Guide*, pp. 17-23]

**i. Institutional Oversight** [*Guide*, pp. 17-19]

**1)** List the institutional entities (units, departments, personnel, *etc*.) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g.,remote offices to which personnel must report).

The Center's Safety Management Team is responsible for the overall management of the Occupational Safety and Health Program. This team consists of safety professionals in a variety of disciplines with experience in radiation safety, biosafety, industrial hygiene, occupational safety and environmental management. The team has oversight of the various occupational medical programs within the Center as described below.

The Center's medical evaluation and preventive medicine program is provided under contract by Federal Occupational Health (FOH). A Contract Officer Representative (COR) from the FDA Safety Office is responsible for monitoring the program. The MOD-1 Health Unit provides all government employees including ORISE Fellows on the Muirkirk Road Campus with the opportunity for an annual physical examination with supporting laboratory tests. The Moffett Center has developed an Injury and Illness Prevention Plan and has reached an agreement with the local occupational health provider, EXCEL, to provide medical care. Medical care is provided to the GCSL

personnel through an Interagency Agreement with the Army Corps of Engineers in Mobile, Alabama. Animal husbandry personnel receive an annual physical by a certified OHMS physician through their contracting company Priority One Services Inc.

**2)** Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

The Center's Safety Management Team is responsible for overall management of a comprehensive safety, occupational health, radiation safety and environmental safety program.
Safety personnel are responsible for providing consultations, interpreting guidelines and policies, and providing training and technical support on laboratory and animal research safety, radiation safety, hazard identification and control, chemical and radioactive waste management, safety inspections, emergency response and environmental issues. The staff reviews and approves research protocols to ensure that experimental procedures minimize personnel and workplace exposure to hazardous agents. Risk assessment is an important part of the safety review process and is used to determine the level of protection that is needed in any given situation. The basis for this risk assessment follows the guidelines published in "The Occupational Health and Safety in the Care and Use of Research Animals".

The Safety Management also maintains and ensures compliance with the Specific Radioactive Materials License issued by the Nuclear Regulatory Commission to FDA/CFSAN. The Radiation Safety Officer oversees the day-to-day operations of the radiation safety program for scientists and support personnel using radioactive materials. The Radiation Safety Officer administers the following Radiation Safety Program elements: decommissioning, decontamination, radioactive material survey control, area contamination surveys, personnel monitoring program, radiation training, radioactive waste management, review and approval of proposed protocols to ensure that experimental

procedures are radiologically sound as well as safe. The Radiation Safety Officer has authority to revoke or suspend the privilege of obtaining or using radioactive material.

The Safety Management Team has developed and maintains the Center's Chemical Hygiene Program Manual, Hazardous Waste Program Manual, Radiation Safety Program Manual and CFSAN Safety Policies and Procedures. Hazard identification and risk assessment are accomplished through information contained in "CFSAN - Study Protocol" form (Form ASP01 Version 6: Revised 17 May 2017) (Appendix 3). The principal investigator identifies the nature of the hazard(s) involved and specifies the safety procedures and guidelines to be followed during the study. Protocols are reviewed by a designated member of the safety team as part of the Center's approval process. In addition, study protocols involving radioactive materials are reviewed and approved by the Center's Radiation Safety Officer, and protocols using select agents are reviewed and approved by the Responsible Official. Safeguards against the identified hazard(s) are selected from the Center's Chemical Hygiene Plan, Radiation Protection Manual, and Hazardous Waste Manual as well as the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories 5th edition and applicable Safety Data Sheets. The principal investigator is responsible for ensuring that all personnel involved in the study are informed of the nature of the hazard(s) and the safety procedures that are to be followed. This is accomplished during the pre-study meeting and by oversight of research activities.

The GCSL is staffed with Collateral Duty Safety Officer (CDSO) and a Radiation Safety Officer and has established a Safety and Health Committee and a Radiation Safety Committee.
Policies and procedures at GCSL are the same as those described above.

The Moffett Center animal facility is dedicated to work with Clostridium botulinum and botulinum neurotoxin. The facility meets the requirements of the Guide for care and use of laboratory animals, and the requirements of the Biosafety in Microbiological and Biomedical Laboratories 5th edition (BMBL) manual for safety for work with viable agents and toxins in mice.

To maintain AAALAC International accreditation, the CFSAN animal research program adheres to the requirements in the *Guide*. The *Guide* requires that "an occupational health program must be part of the overall animal care and use program." In CFSAN, all personnel who have relevant animal exposure or work with animals, their housing

facilities, or non-fixed tissues are required to participate in the FDA Animal Exposure Program (AEP). Personnel identified as having relevant animal exposure will complete the forms required for AEP, the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD-1 health unit.
The Occupational Health Services (OHS) AEP Questionnaire and the Animal Allergy Questionnaire are required to be filled out annually by all personnel who work with animals and/or their non-fixed tissues or have potential exposure to animals as part of their official duties.

The IACUC administrator sends out the AEP questionnaires to identified personnel. The personnel return the completed forms to OHS at the MOD-1 health unit. These forms are used to collect information on potential health issues for those individuals working with animals. Employees are evaluated by the Occupational Health Physician in the MOD-1 health unit. A risk assessment is based on the likelihood of exposure/injury and the consequence(s) of that exposure/injury pertaining to animal care and use, including exposure to non-fixed tissues or other laboratory hazards. The Occupational Health Physician at the MOD1 health unit will provide three (3) levels of clearance for individuals:

1) Fit for work or/fit for duty - specifically applies to animal exposure
2) Clearance with restriction, e.g. "may not work with rabbits" or "may work with rabbits provided the following precautions are taken"
3) Not Cleared - will not be permitted to work with animals or tissues in CFSAN

The Health Summary Form is used to open an Electronic Medical Record (EMR) in OHS to document enrollment and clearances and is updated as needed. The OHS health unit at MOD1 will email a standardized clearance form to the IACUC administrator following the completion of an individual's risk assessment. OHS sends out annual email reminders directly to individuals reminding them of the annual requirement to follow-up with OHS and complete their forms. Participants are offered necessary vaccines, and their health history is documented and maintained in their medical records by OHS.

GCSL is provided with medical services through an Interagency Agreement with the Army Corp of Engineers in Mobile, Alabama.
The Moffett Center is provided with medical services under contract with EXCEL, a private health care provider.

**Contract Personnel (Priority One Services Inc.)**
Contract personnel are required to comply with all aspects of the

Hazard Communication Program. The program is designed to ensure that consistent and uniform information concerning hazardous agents present at the project site is provided to employees to foster awareness of the hazardous agents with which they work, and engender familiarity with the procedures and practices necessary to control exposure. The program was developed in accordance with standards promulgated by OSHA
in 29 CFR Part 1910. Included are such aspects as requirements for labeling and other forms of warning and instruction on Safety Data Sheets. The program is designed to ensure accomplishment of tasks described in the following paragraph:

The on-site Contract Manager
• Reviews all accident reports for accuracy
• Aids Assistant Manager in providing initial and periodic training to employees
• Prepares quarterly facility safety report with recommendations for corrections
• Updates OSHA Form 300 for work-related injuries and illnesses
Contract Personnel Supervisors
• Review, and make available Safety Data Sheets for chemicals used in areas where project personnel are stationed
• Ensure that containers are properly labeled with the chemical name and appropriate hazard warning
• Monitor staff activities to ensure that personnel are following all appropriate safety procedures
Contract staff:
• Use approved GHS labels that identify the chemical name and contain appropriate hazard warnings
• Use information and training received to protect themselves and their fellow workers against potential exposure to safety hazards
• Report to their supervisor any unsafe condition in the workplace

**3)** Describe methods and frequency of reassessing work-related hazards.

The Center's Safety Management Team is responsible for the overall management of the Occupational Safety and Health Program. This team consists of safety professionals in a variety of disciplines with experience in radiation safety, biosafety, industrial hygiene, occupational safety and environmental management. The

team has oversight of the various occupational medical programs within the Center as described below.

The Center's medical evaluation and preventive medicine program is provided under contract by Federal Occupational Health (FOH). A Contract Officer Representative (COR) from the FDA Safety Office is responsible for monitoring the program. The MOD-1 Health Unit provides all government employees including ORISE Fellows on the Muirkirk Road Campus with the opportunity for an annual physical examination with supporting laboratory tests. The Moffett Center has developed an Injury and Illness Prevention Plan and has reached an agreement with the local occupational health provider, EXCEL, to provide medical care. Medical care is provided to the GCSL personnel through an Interagency Agreement with the Army Corps of Engineers in Mobile, Alabama. Animal husbandry personnel receive an annual physical by a certified OHMS physician through their contracting company Priority One Services Inc.

Through the FDA Animal Exposure Program (AEP), personnel identified as having relevant animal exposure will complete the forms required for AEP, the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD-1 health unit. An assessment will be done annually.

Work-related hazards are re-assessed though the required participation in the Occupational Health Services (OHS) AEP on an annual basis as well as through the completion of a risk assessment for all submitted protocols to include initial, renewed or amended. Additionally, risk assessments pertaining to work-related hazards are conducted by designated members of the safety team as needed for work-related injuries, incidents or near-misses as well as for any changes in policy, research procedures or practices that may pose any additional or new hazards.

**4)** Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

All exposures and injuries must be reported to the immediate supervisor, the onsite Occupational Health Center, and the Safety Management Team as described in CFSAN Policy and Procedure Directive 2130.3, Occupational Safety and Program, Accident, Reporting, and Records. The Safety Management Team investigates all recordable injuries and illnesses and responds to spills of chemical, infectious and radioactive materials. All recordable injuries and illnesses are recorded on the Center's OSHA 300 log by means of the Department of Labors (DOL) Employees' Compensation Operations and Management Portal (ECOMP).

FDA also uses The Workplace Incident Manager (WIM) module (as needed) which is designed to improve upon the existing FDA incident reporting system. The goal of this incident reporting is for the collection of data to drive evidence-based improvements to the laboratory science, laboratory security, environmental, and occupational safety and health programs at the FDA. In SIPS, all incident reporting data is stored within the system, the system generates alerts to users that action is required.

**ii. Standard Working Conditions and Baseline Precautions**

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

**1) Medical Evaluation and Preventive Medicine for Personnel** [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

**a)** Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

In CFSAN, all personnel who have relevant animal exposure and or work with animals, their housing facilities, or who work with non-fixed tissues are required to participate in the FDA Animal Exposure Program (AEP). Personnel identified as having relevant animal

exposure will complete the following forms required for AEP: the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD-1 health unit. The Occupational Health Services (OHS) AEP Questionnaire and the Animal Allergy Questionnaire are required to be filled out annually by all personnel who work with animals and/or their non-fixed tissues or have potential exposure to animals as part of their official duties.

In CFSAN, participation in the AEP is mandatory for personnel who have relevant animal exposure and no exemptions will be issued.

**b)** Describe provisions for allowing an individual (following completion of individual health and job related risk assesments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
*Note: Do not include names of the personnel*

In CFSAN, for personnel who have relevant animal exposure, participation in the AEP medical risk assessment is mandatory and there are no exemptions. Personnel that decline the AEP medical risk assessment will not be allowed to work with animals and will have access to the vivarium revoked.

**c)** Describe provisions for assuring confidentiality of medical information.

All medical records will remain confidential. Once the electronic medical record is established, it will allow virtual interaction between employees and clinic staff and help ensure privacy of personal health information. Only the Federal Occupational Health/Occupational Health Service Medical Providers have access to medical records and they are required to  follow all HIPPA regulations.

**d)** Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Contractors must be enrolled in a AEP from their employer.

**e)** Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

The Food and Drug Administration does not require pre- employment or pre-assignment physicals. However, FDA has a comprehensive Occupational Health Surveillance Examination Program (OHSE) available for all CFSAN employees. All CFSAN employees who work with animals or have relevant exposure to animals must participate in the Animal Exposure Program (AEP) medical risk assessment program.
The OHSE program is designed to monitor the health of employees whose work regularly poses the possibility of exposure to hazardous materials.
Public Health Service Officers may elect to use the services provided in a USPHS health program. The Safety Management Team coordinates the occupational health program with the MOD-1 Occupational Health Center.

The Occupational Health Services staff of Federal Occupational Health staff is the health unit staff. The Occupational Health Surveillance Examination Program includes the following components at the indicated frequency:

| | |
|---|---|
| • Blood Profile | Annually |
| • Urinalysis | Annually |
| • Electrocardiogram | (over 36 years of age) Annually |
| • Pulmonary Function | Annually |
| • Visual Acuity | Triennial |
| • Hearing Test | Triennial |

| | |
|---|---|
| • PPD Test | As Needed |
| • Tetanus Booster | Ten Years |
| • Complete Medical Examination | Triennial |
| • Special Tests | As Needed |
| • Other Vaccinations | As Needed |

The Center's medical evaluation and preventive medicine program is provided under contract by Federal Occupational Health (FOH). A COR from the FDA Safety Office is responsible for monitoring the program. MOD-1 has an Occupational Health Center on-site. One registered nurse provides occupational health services to Federal personnel working in the facility and emergency medical services to contract personnel. The center is staffed from 7:30 AM until 4:30 PM on weekdays. A physician spends 2 hours a week reviewing patient information and clinical records gathered over a week's time by the nursing staff.

MOD-1 animal facility contractors are responsible for the protection of their personnel and are required to demonstrate a capability to develop and implement occupational safety and health programs that address the variety of workplace conditions and potential hazards that may be encountered while providing the required services.
The health status of animals is monitored by the veterinary staff by means of vendor reports and the sentinel program. If animals are required for a study that may that pose a zoonotic exposure a risk assessment is performed and procedures including but not limited to PPE, housing, and vaccination are developed to minimize exposure. If a zoonotic exposure were to occur, the individuals potentially exposed would be contacted and referred for medical attention.

Personnel exposed to potentially hazardous agents are trained by their respective supervisors and the Safety Management Team regarding the hazards and counter measures that can be taken to minimize those hazards. The information is also provided during pre-study meetings conducted prior to study initiation. The use of hazardous agents must be listed in the protocol and approved by the Safety Management Team.

Procedures are also in place for personnel that experience animal bites, scratches, needle sticks, or other injuries to report to the local Health Unit for treatment.

**Priority One Services, Inc., Contract Staff**
Contractors develop and implement an occupational health and safety program for contract personnel that include medical evaluation

and preventive medicine. Programs comply with Federal, state, and local regulations for OSHA, EPA, and the State of Maryland, as well as FDA safety and health policies and procedures. Contract personnel are required to participate in the occupational medicine program. The Contract Manager ensures that employees participate in the medical surveillance program.

The Occupational Health Medical Surveillance Program (OHMS) examination schedule consists of an initial examination for new employees before assignment (pre-placement) and an annual examination if the employee is to continue with the same type of assignment. Examination at more frequent intervals may be made if considered necessary by the examining physician.
Contract personnel receive initial and annual physicals through Priority One Services, Inc.
Medical examinations include the following procedures:
• Review of medical history, including status of tetanus immunization and allergies to fur, animals, and latex
• Physical examination of vital signs (blood pressure, temperature, and pulse)
• Audiogram (cage wash personnel)
• Urine drug screen
• Laboratory tests (serum chemistry, CBC, urine analysis, and fecal parasites)
• Pulmonary function test
• TB screen (PPD test)
• Tetanus booster, if required
• Vision screen
• Electrocardiogram
• Chest X-ray
• Hearing test
• Other tests as indicated from history of the individual

Medical records are maintained for each employee for the duration of employment. Access to medical records is restricted to the corporate Division Director, and the examining physician(s). The contract manager is provided summaries of an employee's general physical condition as such information may be helpful in adjusting the employee's work environment. The contract manager also provides the CFSAN COR with the OHMS report. The CFSAN COR is responsible for monitoring contractors' Occupational Health and Safety program for compliance with the terms of the contract.

**GCSL**
The GCSL is provided with medical services through an Interagency

Agreement (lAG) with the Army Corp of Engineers in Mobile, Alabama. The GCSL Administrative Officer is the lAG project officer. GCSL personnel are provided with annual medical examinations, blood and urine analyses and other medical surveillance, such as immunizations and spirometry testing.

**Moffett Center**
The Moffett Center has developed an Injury and Illness Prevention Plan and has reached an agreement with the local occupational health provider, EXCEL, to provide medical care. EXCEL has provided general physical exams, respiratory fit tests as well as base-line pulmonary function tests.

In CFSAN, all personnel who have relevant animal exposure or work with animals, their housing facilities, or non-fixed tissues are required to participate in the FDA Animal Exposure Program (AEP). Personnel identified as having relevant animal exposure must complete the forms required for AEP, the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD-1 health unit. The Occupational Health Services (OHS) AEP Questionnaire and the Animal Allergy Questionnaire are required to be filled out annually by all personnel who work with animals and/or their non-fixed tissues or have potential exposure to animals as part of their official duties.

The purpose of the AEP is to provide clinical guidance on surveillance, immunizations, and evaluation/treatment of animal related injuries and illnesses for FDA workers involved in the care and/or use of animals in research. The FDA Chief Medical Officer, Occupational Health Services (OHS) is responsible for the management and monitoring of the FDA AEP.

The IACUC administrator sends out the AEP questionnaires to identified personnel. The personnel return the completed forms to OHS at the MOD-1 health unit. These forms are used to collect information on potential health issues for those individuals working with animals. Employees are evaluated by the Occupational Health Physician in the MOD-1 health unit. A risk assessment is based on the likelihood of exposure/injury and the consequence(s) of that exposure/injury pertaining to animal care and use, including exposure to non-fixed tissues. The Occupational Health Physician at

the MOD-1 health unit will provide three (3) levels of clearance for individuals:

1) Fit for work or/fit for duty - specifically applies to animal exposure
2) Clearance with restriction, e.g. "may not work with rabbits" or "may work with rabbits provided the following precautions are taken"
3) Not Cleared - will not be permitted to work with animals or tissues in CFSAN

The Health Summary Form is used to open an Electronic Medical Record (EMR) in OHS to document enrollment and clearances and is updated as needed. The OHS health unit at MOD-1 will email a standardized clearance form to the IACUC administrator following the completion of an individual's risk assessment. OHS sends out annual email reminders directly to individuals reminding them it is time to come to OHS and complete their forms. Participants are offered necessary vaccines, and their health history is maintained in medical records by OHS.

**f)** Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

For emergency situations, local emergency responders are contacted by dialing 9-911 on any campus telephone. For emergency procedures for exposure/injuries after working hours, an Occupational Medicine Consultants page operator should be called at 301-738-6420. The on-call doctor will return the call.

**GCSL**
For emergency medical situations, local emergency responders are contacted by dialing 9-911. for any emergency 24/7.

**2) Personnel Training Regarding Occupational Health and Safety**
[*Guide*, p. 20]

(b) (4)

(b) (4)

*Note*: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

The Center's Safety Management Team is responsible for overall management of a comprehensive safety, occupational health, radiation safety and environmental safety program.

Safety personnel are responsible for providing consultations, interpreting guidelines and policies, and providing training and technical support on laboratory and animal research safety, radiation safety, hazard identification and control, chemical and radioactive waste management, safety inspections, emergency response and environmental issues. The staff reviews and approves research protocols to ensure that experimental procedures minimize personnel and workplace exposure to hazardous agents. Risk assessment is an important part of the safety review process and is used to determine the level of protection that is needed in any given situation. The basis for this risk assessment follows the guidelines published in "The Occupational Health and Safety in the Care and Use of Research Animals".

The Safety Management Team has developed and maintains the Center's Chemical Hygiene Program Manual, Hazardous Waste Program Manual, Radiation Safety Program Manual and CFSAN Safety Policies and Procedures. Training on the Chemical Hygiene plan is provided initially and as needed while training for the above mentioned manuals are provided annually. Hazard identification and risk assessment are accomplished through information contained in "CFSAN - Study Protocol" form (Form ASP01 Version 6: Revised 17 May 2017). The principal investigator identifies the nature of the hazard(s) involved and specifies the safety procedures and guidelines to be followed during the study. Protocols are reviewed by a designated member of the safety team as part of the Center's approval process. In addition, study protocols involving radioactive

materials are reviewed and approved by the Center's Radiation Safety Officer, and protocols using select agents are reviewed and approved by the Center's Select Agent Responsible Official.

Identified Animal research personnel received training "Safe Practices and Procedures for Animal Research" presented by the Eagleson Institute on October 23 – 24, 2017

**3) Personal Hygiene** [*Guide*, p. 20; *Ag Guide* pp. 4-5]

**a)** List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

**MOD-1**

Animal care personnel employed through the animal husbandry contract wear scrub clothing, dedicated safety shoes, shoe covers, and disposable gloves (nitrile) for routine work within the animal facility. The minimal protective clothing for all other personnel entering the animal facility includes a lab coat dedicated to the animal facility and shoe covers, however personnel can replace the lab coat with scrub clothing. Scrub clothing and cloth coats are laundered on-site by the animal husbandry staff. All personnel entering rooms housing animals must wear disposable gloves. Additional PPE may be required based on the biosafety level and the risk assessment conducted for the study. All required PPE is provided to the staff through the CFSAN animal research program.

**GCSL**

Personal protective equipment consists of cloth coats, disposable nitrile gloves, eye protection, and safety shoes. Knee-high rubber boots and aprons are worn when cleaning tanks and floors. Disposable laboratory coats and shoe covers are worn when working with radionuclides. Cloth coats are laundered by Waite's Medical & Industrial Cleaners.

**Moffett Center**

Personal protective equipment consists of cloth coats, disposable nitrile gloves and eye protection. Cloth coats are laundered by an off-site contractor.

**b)** Describe arrangements for laundering work clothing.

**MOD-1**

Scrub clothing and cloth coats are laundered on-site by the animal husbandry staff.

**GCSL**

Cloth coats are laundered by Waite's Medical & Industrial Cleaners.

**Moffett Center**

Cloth coats are laundered by an off-site contractor.

**c)** Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

**MOD-1**

Male and female locker rooms with shower, hand washing, and clothes changing facilities are provided on each floor for all personnel that enter the animal facility. Sinks and eye wash stations are available in animal holding and treatment rooms throughout the facility. Showering is not required for entry or exit of the animal facility.

PPE is not worn outside of the animal facility except for removing trash from the facility. Staff removes their shoe covers and exits through the return side of cage wash for trash removal. Staff can re-enter the return side of the facility without changing work clothes, but they must put on clean shoe covers prior to re-entering the facility. Staff must change into clean PPE and wash their hands following removal of trash if they wish to enter the supply side of the animal facility.

All personnel must wash their hands prior to exiting the animal facility.

**GCSL**

On entering and exiting the fish holding area, personnel are required to wash hands at a station located at the entrance to the fish holding area (Room 118). A sign has been posted at each exit that reads "Notice to Employees: Wash hands after handling cultures and animals, after removing gloves, and before leaving the animal facility." Clothes changes are not required at GCSL and there are no clothes changing rooms. Wearing of lab coats outside of the animal

facility is prohibited. A shower, if needed after collecting animals, is available in two locations – the mechanical shop (Room 312) or in Room 306.

**Moffett Center**

On entering and exiting the mouse facility, personnel are required to wash hands at a station located outside of Room 409. A sign has been posted that reads "Notice to Employees: Wash hands after handling cultures and animals, after removing gloves, and before leaving the animal facility." Clothes changes are not required and there are no clothes changing rooms. Wearing cloth coats outside of the animal facility is prohibited.

**d)** Describe policies regarding eating, drinking, and smoking in animal facilities.

FDA is a smoke free environment; tobacco use is not permitted in any Agency building.

**MOD-1**

Eating is prohibited in all areas of the animal facility, including the locker rooms. Water fountains are available on each floor of the animal facility for staff use. The building has a cafeteria outside if the animal facility that is available for consumption of food and drink.

**GCSL**

Eating is prohibited in all areas of the animal facility. There is no cafeteria; however, there is a break room for personnel where eating and drinking are permitted (Room 307). A water cooler is available in the main lobby (Room 200) of the building for personnel.

**Moffett Center**

Eating is prohibited in all areas of the animal facility. There is no cafeteria; however, there is a break room for personnel where eating and drinking are permitted.

**4) Standard Personnel Protection** [*Guide*, pp. 21-22]

**a)** Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals).

**MOD-1, GCSL and Moffett Center**

Routine safety inspections are conducted to identify safety problems and to evaluate the adequacy of current policies and procedures. Although the program is designed to be proactive in the identification of and correction of safety issues, management and a designated member of the Safety Management Team reviews injury reports to safety issues.

Procedures utilized at MOD-1 to reduce the potential for physical injury include use of protective equipment and implementation of SOPs.

Types of protective equipment available include:

- ear plugs (used in excessive noise-producing areas)
- eye protection
- face shields (used where the potential for eye injury may occur)
- safety shoes (used where the potential for foot injury may occur)
- various types of gloves (dependent on need for proper hand protection)
- various types of masks (dependent on need for proper respiratory protection as determined by a risk assessment)
- floor matting (reduce potential for slipping and falling in high moisture areas)
- safety chains (used to identify hazardous mechanical equipment areas)
- safety signs (used to identify wet floors, etc.)
- sharps containers (storage of used needles)
- broken glass containers (storage for all types of broken glass)

• protective aprons (used in areas where caustic chemicals are handled)
• step stools
• safety goggles

SOPs are drafted and updated as needed to provide instructional clarification on the safe and proper operation of equipment in the animal facility. SOPs are also used to ensure that the wellbeing of the animals is not compromised while being handled and manipulated during a study.

The MOD-1 facility utilizes pigs for (b) (4) studies. A swine sling is utilized to restrain the animals.

**b)** Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Animals can be a source of allergens. Separation of species is done in the facility. The use of Personal protective equipment (PPE), Biological Safety Cabinets (BSC), chemical fume hoods for animal handling and cage changing are recommended.

Additionally, all personnel who have relevant animal exposure or work with animals, their housing facilities, or non-fixed tissues are required to participate in the FDA Animal Exposure Program (AEP). Personnel identified as having relevant animal exposure must complete the forms required for AEP, the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD-1 health unit. The Occupational Health Services (OHS) AEP Questionnaire and the Animal Allergy Questionnaire are required to be filled out annually by all personnel who work with animals and/or their non-fixed tissues or have potential exposure to animals as part of their official duties.

**c)** Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Animals, animal tissues and excreta are likely sources of zoonoses. The use of Personal protective equipment (PPE), Biological Safety Cabinets (BSC), chemical fume hoods for animal handling and cage changing are recommended.

All personnel who have relevant animal exposure or work with animals, their housing, facilities, or non-fixed tissues are required to participate in the FDA Animal Exposure Program (AEP). Personnel identified as having relevant animal exposure must complete the forms required for AEP, the FDA form 3987, FDA Animal Exposure Program (AEP) Health Questionnaire, the Animal Allergy Questionnaire, and the Health Summary Form, so a risk assessment can be performed by the Occupational Health Physician in the MOD1 health unit. The Occupational Health Services (OHS) AEP Questionnaire and the Animal Allergy Questionnaire are required to be filled out annually by all personnel who work with animals and/or their non-fixed tissues or have potential exposure to animals as part of their official duties.

**GCSL**
Personnel working with fish should wear PPEs such as a lab coat, nitrile gloves, face shield, mask and/or goggles when in the Wet Lab to minimize contact with possible allergens such as being splashed with water.

**d)** Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

Biological Safety Cabinets, Cage Changing Stations, Chemical Fume Hoods and HEPA filtered containment caging is certified on an annual basis by an outside contractor through the CFSAN Safety Team. BSCs and cage changing stations are monitored for proper functioning before use by visual inspection of the magnehelic gauges or the indicator lights present on each cabinet. Chemical fume hoods are monitored by a visual and audible alarm system to ensure proper functioning. Biocontainment caging is monitored for proper functioning by a digital display and audible alarm system. Digital readings are recorded on a daily basis while the caging is in use.

**e)** Respiratory Protection

**i)** Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

Respirators are selected by the CFSAN Safety Team based on a risk assessment. The knockout mice bred in the facility are housed in biocontainment caging that is maintained under positive pressure. All personnel working in these breeding rooms are required to wear N95 respirators. All personnel that are required to wear a respirator are enrolled in the CFSAN Respiratory Protection Program. Employees are fit tested on an annual basis and receive training on the proper use of the N95 respirator through the CFSAN Safety Team.

**ii)** Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

CFSAN Safety Team notifies the Occupational Health services physician so a medical clearance can be done on personnel identified to wear a respirator. Individuals must be cleared by the physician to participate in respirator fit testing.

**iii)** Describe how such respiratory protective equipment is selected and its function periodically assessed.

Respirators are selected by the CFSAN Safety Team based on a risk assessment.

**f)** Heavy Equipment and Motorized Vehicles

**i)** Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
*Note:* Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

**MOD-1**

A series of PowerPoint presentations have been developed by animal husbandry personnel working in the MOD-1 cage washing facility. The presentations are used for training personnel and are available for review. A Cage Wash Safety Poster has also been developed based on these presentations and is posted in the cage washing area. Presentations are available upon request.

The Rack Washer has both a Red Emergency Pull Cord and an Emergency Push Button. Both are checked on a weekly basis. The emergency pull cord is located inside of the rack washer and is used to stop the machine if an individual is inside the washer when it is activated. Pulling this cord will automatically shut off the machine and keep the machine from operating.

The pull cord must be reset in order to restart the machine. The emergency push button is located on the outside of the rack washer just below the control panel on the return side of the equipment. Pushing the red button stops the machine and keeps the machine from running. Controls on the rack washer must be reset to use the machine.

There are Emergency Push Buttons located on both tunnel washers below the control panel on the return side of the washers and next to the exit on the supply side of the washers. Both are checked on a weekly basis. Pushing the red button stops the machine in whatever cycle it is running. The machines must be reset to resume use of the tunnel washers. Signage has been placed in the rack and tunnel washers to clearly indicate where to push to open the doors from inside of the machines.

**GCSL and Moffett Center**

Not applicable

**ii)** List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

**MOD-1**
Not Applicable

**GCSL**
• A pick-up truck is used to obtain freshwater fish. Personnel driving a government vehicle must undergo mandatory training every two (2) years
• A boat is used to obtain marine species. The Marine Operations SOP is followed
• A (b) (4) is used to transport fish from the boat or truck to the animal holding facility; drivers must undergo mandatory (b) (4) training every two (2) years

**iii)** If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

**MOD-1 and Moffett Center**
Not Applicable

**GCSL**
Fish are moved in a transport tank located in the back of a pick-up truck. Gloves (nitrile) are worn when loading the fish into the tank and again when transferring the fish to the control tanks in the Wet Lab. The driver does not come into contact with the fish.

**g)** Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

**MOD-1**
Scavenging of anesthetic gas is through an attached charcoal filtered canister with supplemental exhaust into a central vacuum system that is located in the surgical area. The CFSAN Safety Management Team performs monitoring of personnel for exposure to volatile anesthetic agents as requested.

**GCSL and Moffett Center**
Not Applicable

**iii. Animal Experimentation Involving Hazards** [*Guide*, pp. 20-21]

**1)** List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

**a)** Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

All animal protocols that include the use of biological, chemical, or physical agents must be approved through the CFSAN Safety Team as part of the Center's review and approval process. Written operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents are reviewed and approved by the IACUC and the Safety Team. These SOPs are available to all animal research staff as hard copy or through the program electronic portal. Additional SOPs may be required for a specific protocol; these procedures are reviewed as part of the protocol. Protocol specific SOPs are provided to research and contract staff working on the specified protocol. Biosafety manuals including specific SOPs are generated for work with botulinum neurotoxin as required by the 5th edition of the BMBL.
CFSAN staff must show that they have received proper training in the use of any (b) (4) prior to the commencement of work. The CFSAN Safety Team and the Principal Investigator generally provides

training on use of (b) (4) however additional training from outside entities may be provided depending on the hazard.

**MOD-1**
Currently:
**BSL-2**

*Clostridium botulinum*

**GCSL and Moffett Center**
There are no active protocols using vertebrates at this time, therefore, no hazardous materials are being used.

**b)** Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

Currently:
**MOD-1**
Toxins:
Botulinum toxin
Adjuvants
Freund's Complete and Incomplete Adjuvants

**GCSL and Moffett Center**
There are no active protocols using vertebrates at this time, therefore, no hazardous materials are being used.

**c)** Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

Specific SOPs for research utilizing radioactive isotopes are generated and reviewed under the guidance of the CFSAN Safety Team and the Radiation Safety Officer.

**2) Experiment-Related Hazard Use** [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
*Note:* Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents

should be available during the site visit.

**a)** Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

The Center's Safety Management Team is responsible for overall management of a comprehensive safety, occupational health, radiation safety and environmental safety program.
Safety personnel are responsible for providing consultations, interpreting guidelines and policies, and providing training and technical support on laboratory and animal research safety, radiation safety, hazard identification and control, chemical and radioactive waste management, safety inspections, emergency response and environmental issues. The staff reviews and approves research protocols to ensure that experimental procedures minimize personnel and workplace exposure to hazardous agents. Risk assessment is an important part of the safety review process and is used to determine the level of protection that is needed in any given situation. The basis for this risk assessment follows the guidelines published in "The Occupational Health and Safety in the Care and Use of Research Animals". Those with relevant animal exposure must be enrolled in AEP and assessed by FOH physician.

**b)** Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

Risk assessments are done by Safety Team, and personnel are enrolled in AEP and assessed by FOH physician.

**c)** Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

The Safety Management Team has developed and maintains the Center's Chemical Hygiene Program Manual, Hazardous Waste Program Manual, Radiation Safety Program Manual and CFSAN Safety Policies and Procedures. Hazard identification and risk assessment are accomplished through information contained in "CFSAN - Study Protocol" form (Form ASP01 Version 6: Revised 17

May 2017). The principal investigator identifies the nature of the hazard(s) involved and specifies the safety procedures and guidelines to be followed during the study.

**d)** Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

Risk assessments are done by Safety Team, and personnel are enrolled in AEP and assessed by FOH physician.

**3)** (b) (4) **Training for Personnel** [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Staff members working with infectious agents are required to attend a mandatory (b) (4) training course. Training topics include: hazard identification, standard microbiological practices, special microbiological practices and the use of safety equipment and personal protective equipment.
Personnel working with materials of human origin are also required to attend the Center's (b) (4) Program.

Personnel working with chemical agents are required to attend mandatory (b) (4)
courses. Training topics include: identification of chemical and physical hazards, the OSHA Lab Standard, safe work practices, personal protective equipment, engineering controls, administrative controls, emergency procedures and waste management. The Safety Team provides chemical exposure evaluations, including volatile agents such as isoflurane, as needed. Personnel using respiratory protection are enrolled in the respiratory protection program and receive training and fit testing from the Safety Team.

The radiation safety program requires that Study principal investigators must have a minimum of 40 hours of (b) (4)
training and three years of experience working with radioactive material, accompanied by annual training. Study personnel must attend eight hours of radiation safety training and receive hands-on training from the study principal investigator. Personnel who are required to enter a radioactive materials work area must attend four hours of a (b) (4) training course.

**4) Facilities, Equipment and Monitoring** [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and containment levels (if appropriate).
*Note:* If preferred, information may be provided in a Table or additional Appendix.

**MOD-1**
The following space within the MOD-1 vivarium is available for research with hazardous chemicals and compounds and BSL-2 pathogens.

| Space Designation | First Floor | Size ($ft^2$) | Second Floor | Size ($ft^2$) |
|---|---|---|---|---|
| Holding Rooms | 21 | 1,803 | 43 | 7,701 |
| Procedure Rooms | 4 | 480 | 3 | 1,124 |
| Surgery (including surgery preparation | 2 | 470 | 1 | 227 |
| Necropsy | 2 | 1,008 | 0 | - |
| **TOTAL** | **29** | **3,761** | **47** | **9052** |

The MOD-1 vivarium is a dual corridor facility that allows entry and exit of animal rooms through separate corridors. This design limits movement of hazardous materials within the animal facility and between animal holding and treatment rooms. The vivarium is provided with single pass air that flows from clean to dirty preventing movement of hazardous materials through the HVAC system. The HVAC system that services the animal facility is separate from the systems for administrative and laboratory space. The HVAC system for the animal facility is provided with emergency generator power to maintain heating, cooling and the pressure differentials in the event of the loss of commercial power. The differential air pressure for each room is individually controlled so that directional air flow can be adjusted to contain hazardous materials. Customarily the pressure differential of air within the animal facility is maintained at highest pressure in the supply- side corridors, intermediate pressure in animal rooms, and lowest pressure in return-side corridors resulting in air flow from supply to return corridor. However, air pressure can be maintained negative to the animal room in both corridors if required by a particular study. A visual directional air flow indicator is mounted over each animal room door in the supply corridor to confirm air flow for each room. Air flow is also monitored by computer on a continual basis by the

Operations and Maintenance (O&M) staff. The animal facility provides Class II Type A2 Biological Safety Cabinets (BSC) for studies using microbial pathogens and toxins, and rooms with chemical fume hoods are available for studies that utilize chemical hazardous materials. The necropsy suite has both a BSC and chemical fume hood to accommodate (b) (4) studies. All BSCs and chemical fume hoods are certified on an annual basis through the Safety Team by an outside contractor. Animal holding and treatment rooms are equipped with sinks and eye wash stations, and showers are available on each floor.

The MODI vivarium also has one animal room dedicated (posted) for work with radioactive materials. There are no active protocols utilizing radioactive materials, and there are no future plans for such research. If research were to resume, it would be conducted in compliance with CFSAN's NRC limited scope license.

All studies within the MOD-1 vivarium including those in the specialized areas are supported by a 129 $ft^2$ animal receiving bay, a 624 $ft^2$ bedding storage area, and male and female locker rooms on each floor. The facility has a 3,880 $ft^2$ cage wash area on the supply side of the facility for marshalling sanitized materials, and a 4,880 $ft^2$ area on the return side of the facility for sanitizing caging and other associated items. A pass-thru autoclave is available in the return side of the cage wash area to decontaminate caging and other materials prior to sanitization. This area also has Class I animal bedding disposal units to handle soiled bedding. The disposal units are certified on an annual basis by an outside contractor.

The MOD-1 facility has 1 quarantine room (220 $ft^2$ each) for quarantine of newly arrived animals if required based on the animal health report provided from the vendor. If animal health precludes moving the animals to conventional housing within the facility (e.g.., harboring an infectious agent) studies can be conducted in the quarantine space.

***Gulf Coast Seafood Laboratory***

| *Designation* | Room Number(s) | Size ($ft^2$) |
|---|---|---|
| *Freshwater and Seawater Head Tanks (Outdoor)* | | 296 |
| *Fish Holding-Procedure/Wet Lab* | 118 | 732 |
| *Necropsy and Surgery* | 119 | 165 |
| *Cage/Implement Washing* | 122 | 102 |
| *Laboratory Space* | 144, 100, 102-108, 110, 120 | 1,648 |
| *-80° C Storage Freezer* | 116 | 325 |
| *-20° C Storage Freezer* | 109 | 82 |
| *4° C Storage Refrigerator* | 111 | 82 |

| | | |
|---|---|---|
| *Dry/Ambient Temperature Storage* | 308 | 936 |
| Hazardous Waste Storage | 303 | 100 |
| Hazardous Waste Storage-Radioactive | 302 | 70 |
| Seawater Pump House and Emergency Generator | 315 | 200 |
| Main Generator House | 313 | 136 |
| Diesel Fuel Tank | Next to 313 | 10,000 gal |
| Office and Administrative Space | 201-205, 206-211 and 212-217 | 3,945 |
| **TOTAL** | **36** | **8,523** |

Exposure of animals to aquatic biotoxins, aquaculture drugs, or radionuclides does not require special housing or care requirements. The potentially hazardous agents used are non- volatile, rapidly metabolized or quickly captured by disposable filtration media. Aquatic biotoxins are rapidly degraded upon exposure to water. Radionuclides are used under NRC license restrictions and are of low specific activity. Personnel working with radionuclides are not required to wear radiation exposure badges; however, radiation swipe tests of all areas exposed to radioactivity are performed after each use or exposure.

**Moffett Center**

| Designation | Room Number(s) | Size ($ft^2$) |
|---|---|---|
| Animal Holding | 409 | 153 |
| Animal Procedure | 411 | 289 |
| Cage Washing | 412 | 60 |
| Administrative | 365, 378 | 405 |
| Loading Dock | | 144 |
| Storage Area | B100 | 30 |
| **TOTAL** | **6** | **1,081** |

Animal work at the Moffett Center is limited to the study of *Clostridium botulinum* and botulinum toxin in mice. The animal facilities utilized for this work are registered with the National Select Agent Program and meet the requirements of the 5th edition of the BMBL. The animal facility is serviced by a dedicated HEPA-filtered exhaust system that is provided emergency generator power. Mice are housed in disposable microisolator caging that is handled as hazardous waste. All animal manipulations are conducted in Class II Type A2 biological safety cabinets that are certified on an annual basis through the Safety Team by an outside contractor.

**b)** Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

Terminal animal procedures have been conducted in laboratories, where the animals were transported to the laboratories through common use corridors in MOD-1. Animals were transported in standard, disposable, polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops are used. Terminal animal procedures conducted in laboratories has been discontinued.

**c)** Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

**d)** Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

**MOD-1**
Prior to initiation of an approved study, a pre-study meeting is scheduled. All Government and contract staff involved with conduct of the study are required to attend. Information is shared to clarify issues regarding details for study implementation that includes but is not limited to review of protocol-specific SOPs in support of the study, hazardous agents associated with the study, PPE, and routine husbandry for the study.

Center managers, Principal Investigators, the CFSAN Safety Management Team, the IACUC, and the AHU Contract Managers as a team are responsible for personnel safety.
Several oversight processes are in place to ensure fulfillment of the safety program. Part of the Post Approval Monitoring (PAM) program is confirming that all personnel are using the correct personal

protective equipment (PPE) as described in the study protocol and required by program Standard Operating Procedures (SOP). The AHU management is responsible for ensuring that all contract staff are using the correct PPE as described in specific protocols and SOPs. The IACUC also provides oversight during semiannual facilities inspections.

Principal Investigators are responsible for ensuring that all study personnel are using the prescribed PPE. Observations for compliance with personnel safety requirements include compliance to approved study protocols and SOPs, contractor and facilities SOPs, as well as Federal, state, and regional requirements. If a noncompliant activity is observed, a correction is made on the spot and the non-compliance is reported to the IACUC. Reporting is either through direct reporting to a member of the IAUC or documented on the PAM report if observed during PAM observation. A preventative measure to minimize recurrence is instituted and follow-up observations put into place.

Studies involving BSL-2 agents in rodents are monitored by the PI, veterinary staff, Biosafety Officer, and through the Post Approval Monitoring (PAM) Program. Minimal PPE for (b) (4) studies includes scrubs and a lab coat or disposable coverall, eye protection, double shoe covers and double gloves (nitrile). Cages are changed in a BSC and all contaminated materials are packed into autoclave safe bags in the BSC. The contaminated materials are autoclaved using the pass-thru autoclave available in cage wash. Disposable autoclaved materials are then packaged into boxes and removed for off- site incineration by a licensed contractor. Mouse carcasses are not autoclaved but are packaged as biohazardous waste and removed for off-site incineration by a licensed contractor.
Rodent carcasses can be autoclaved prior to disposition if requested by the investigator. After autoclaving non-disposable materials are sanitized in tunnel and rack washers.

Rodents are the only animal species in the MOD-1 facility exposed to hazardous chemicals. Minimal PPE includes a disposable lab coat, shoe covers, gloves (nitrile), and eye protection. A risk assessment is conducted by the CFSAN Safety Team for each hazardous chemical utilized in rodents. This risk assessment determines if additional PPE is necessary for the study. If necessary, rooms are available that have chemical fume hoods for animal handling and cage changing.
The Safety Team also determines the waste streams for handling animal carcasses, and solid and liquid waste generated during the study. Following any protocol specific treatment, the caging and enrichment devices are sanitized in tunnel and rack washers.

**GCSL**
Study personnel for (b) (4) studies are required to wear lab coats and gloves (nitrile) when working with any potentially hazardous agent. When working with radionuclides, research personnel wear disposable lab coats and shoe covers. Personnel working with radionuclides are not required to wear radiation exposure badges due to the nature of the isotopes used, however radiation swipe tests of all areas exposed to radioactivity are performed after each use or exposure. Fish carcasses are incinerated at the conclusion of the study.

**Moffett Center**
Prior to the performance of duties for any study, a pre-initiation meeting is held between the PI and a member of the Moffett Center Animal Facility (MCAF) management and other responsible MCAF staff to discuss the protocol. Topics to be discussed include but are not limited to technical support aspects, required training, safety issues, and potential conflicts in scheduling. The MCAF management and the PI are responsible for oversight of the study, with input from the veterinarian and the biosafety officer. PPE includes eye protection, lab coats, shoe covers, surgical mask, hair cover and gloves (nitrile). Mice at the Moffett Center are housed in the facility for a maximum of 5 days so cage changing is not routinely conducted. If necessary, cages are changed in a BSC. Mice are housed in disposable cages that are disposed of as biohazardous waste at the conclusion of the study. The biohazardous waste is removed off-site by a licensed contractor. Mouse carcasses are also treated as biohazardous waste and removed for incineration.

**e)** Incidental Animal Contact and Patient Areas

**i)** List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

Terminal animal procedures have been conducted in laboratories, where the animals were transported to the laboratories through common use corridors in MOD-1. Animals were transported in standard, disposable, polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops are used. Terminal animal procedures conducted in

laboratories has been discontinued.

**ii)** Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

**MOD-1**
Newly arrived animals are transported from the dedicated animal receiving bay to the animal facility through a common use corridor on the ground floor of the animal facility. The shipping boxes containing rodents and rabbits are wiped with disinfectant and placed in a closed, stainless steel transport cart and moved into the animal facility. Pigs are transported in dog cages. The transport carts are sanitized after each use.

For animal procedures conducted in a laboratory outside of the animal facility, the mice for these protocols are placed in clean microisolator cages and transported to the laboratory in a closed, stainless steel transport cart. Animal transport to the laboratory uses a traffic pattern that allows for minimal utilization of common use corridors. The animal carcasses and soiled caging is placed in biohazard containers and transported to the return side of cage wash using closed, stainless steel transport carts. The transport carts are sanitized after each use. There are no current protocols that require animal procedures in the laboratory.

**GCSL and Moffett Center**
Not Applicable

## B. Program Oversight

### 1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

#### a. IACUC/OB Composition and Function [*Guide*, pp. 17; 24-25]

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

**i.** Describe Committee membership appointment procedures.

The designated Institutional Official for CFSAN, Dr. Mary Torrence, DVM, Ph.D., DACVPM., appoints members of the IACUC. The authority to appoint CFSAN IACUC members was transferred, along with all other Institutional Official authorities and responsibilities, by memo of May 24, 2018 from the Center Director, the Chief Executive Officer, to the Director of Office Applied Research and Safety Assessment (OARSA).

**ii.** Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

Meetings are scheduled for the third Tuesday of each month to review research and testing activities involving the care and use of animals. A quorum is defined as a simple majority. If necessary, the committee meets in extra session(s) at the request of the IACUC Chairperson. The semi-annual inspections are held in April and October.

**iii.** Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

The budget for IACUC training falls under the Office Applied Research and Safety Assessment. Funds are available for training, training material, training travel, and other Committee-related expenses. Committee members request training through the IACUC Chairperson. Funding is provided for committee members to attend the annual National Capital Area Branch meeting of AALAS, and funds are available each year for members to attend IACUC 101/201 training. In addition, members are made aware of local training opportunities available at other institutions, such as NIH/Bethesda, USUHS/Bethesda, and the University of Maryland. Upon request, each nonaffiliated member is provided with a lap-top personal computer and printer to permit communication with other Committee members and access to Internet training and other animal care and use information on the Web. The Chairperson maintains an e-mail list to communicate these types of events to Committee members. Committee members are invited to participate in training activities sponsored by the Center that deal with animal care and use, occupational health and safety, and regulatory issues impacting on research.

AII IACUC members are provided copies of the 8th edition of the Guide *for the Care and Use of Laboratory Animals*, the PHS Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act, and The IACUC Handbook, 3rd edition (Edited by: J. Silverman, D.V.M., M. A. Suckow, D.V.M., and S. Murthy, Ph.D.; CRC Press, Boca Raton, FL; 2014). An IACUC specific electronic drive share is also maintained that contains

pertinent articles pertaining to animal welfare.

An IACUC share drive accessible only to IACUC members has been developed. This drive contains standard operating procedures for (b) (4) studies, institutional policies, documents pertinent to IACUC proceedings (e.g., minutes of IACUC meetings, approved amendments and protocols), reference materials (PHS policy, 2013 Report of the AVMA Panel on Euthanasia) and related information. A second share drive is available to all principal investigators and CFSAN personnel interested in conducting animal research. The resource share drive provides reference material and guidance on developing an animal research protocol, standard operating procedures for (b) (4) studies, Institutional policies, and pertinent animal reference materials.

**Recent Committee training:**

IACUC members ((b) (5)
(b) (5) )
attended (b) (4)
.
(b) (5) attended (b) (4)

Attending Veterinarian training:

(b) (4)

IACUC members are attending (b) (4)
.

https://www.citiprogram.org/index.cfm?pageID=154&icat=0&clear=1

**b. Protocol Review** [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

**i.** Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

*Note:* Make sure you address each of the items above.

All protocols including research, teaching, and (b) (4) studies are reviewed and approved by the IACUC. The CFSAN animal research program is internally funded; studies funded through a grant proposal are not typically encountered in the animal program. Protocols for proposed studies received for IACUC approval have been reviewed and approved by the line managers of the Principal Investigator and the Safety Management Team. All studies that include select agents are required to have a signature from the Responsible Official or Alternate Responsible Official prior to submission of the protocol for review. Protocols and accompanying items (e.g., SOPs, memos, and related documents) are submitted to the Executive Secretary of the IACUC not less than six working days prior to a meeting (i.e., no later than close-of-business of the seventh working day before the regularly scheduled third-Tuesday- of- the-month meeting date) for distribution to committee members, placement on the agenda, and review. Each protocol is assigned a unique IACUC number in simple numerical order of receipt.

Protocols are distributed to Committee members through a secured electronic communications portal. Use of telecommunications is in accordance with the NIH N Notice NOT-0D-06-052, of 24 March 2006, Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals. Members without access to the electronic communications portal (e.g. Non-affiliated Members) receive hard copies of the protocols from the IACUC Executive Secretary. Meetings for protocol review are conducted by the Chairperson, Vice Chairperson or their designee, and a quorum of

members is required for protocol review.

Protocols are subjected to an initial full committee review convened quorum of the members of the IACUC that entails an open discussion by all present committee members on all aspects of the protocol. Following protocol review a motion is made by a member of the committee on one of the possible outcomes outlined below. A second of the motion is required prior to full committee vote. A poll of the committee is conducted on the motion and the motion is carried by majority vote. Dissenting votes are recorded in

the minutes of the committee meeting. Full IACUC review may result in approval, a requirement for modifications (to secure approval), or withholding of approval. Full committee review must occur during a convened meeting of a quorum of the IACUC members, and with a formal vote.

The other method of IACUC review is designated member review (DMR) by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review. Designated member review may be utilized only after all members have been provided the opportunity to call for full-committee review. If any member requests full committee review then that method must be used. If not, the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). Designated review may result in approval, a requirement for modifications (to secure approval), or referral to the full committee for review. Designated review may not result in withholding of approval.

If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

Study protocols are required to identify the USDA code for exposure of animals to pain, distress, or discomfort as described in USDA Policy #11. In committee review, the protocol is assessed for appropriateness of the category identified, inclusion of necessary information and, if category "E" is identified, the required scientific justification for the study. When the appropriate pain/distress category for a procedure is uncertain, the principal investigator is advised to list the more painful/distressful level that applies. If study results demonstrate that a lesser level is more accurate, the principal investigator is asked to amend the protocol with an explanation of the basis for the decision to serve as a guideline for other investigators and future studies.

The FDA has developed a policy that prohibits lethal dose (b) (4) studies, and the Center's policy is that procedures involving animals shall avoid or minimize discomfort, distress and/or pain. If unavoidable, then a written scientific justification is required with CFR references or other guidelines, as appropriate. A literature search for alternatives utilizing at least two (2) databases is required to support studies causing pain or distress. The literature search must address the need for the research activity, that the research is not a duplication of work, and that an alternative is not available. For protocol development, principal investigators are encouraged to discuss exposure of animals to procedures that cause pain and/or distress with the veterinary staff for the appropriate categorization and guidance relative to the consideration of alternatives to painful/distressful procedures that is enunciated in USDA Policy #12. During protocol review, all studies are evaluated on the potential adverse effects of the study and the potential benefits that may result from the research. Prior to approval, the committee must determine that the benefits outweigh the potential pain and distress experienced by the animal.

The Protocol Form requires investigators to justify the number of animals requested and provide any statistical methods that will be used. One voting member of the CFSAN IACUC is a statistician who is responsible for determining that the animal numbers are appropriate for the study. PIs are encouraged to discuss animal numbers and group size with the statistician during protocol development.

All studies conducted in the MOD-1 vivarium are overseen through the Post Approval Monitoring Program. Studies that involve potential pain and distress are also monitored by the Veterinary Staff. Studies at the GCSL and the Moffett Center are monitored by their member of the IACUC respectively.

**ii.** Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a description/definition of “major” vs. “minor” amendments.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

All changes to a protocol are submitted to the IACUC Chairperson by the Principal Investigator on Amendment to Protocol Form 3244a.

Amendments are submitted to the IACUC Chairperson and then sent to the full committee for initial review. The committee will indicate whether an amendment can be reviewed by 1) full-committee review by a convened quorum of the members of the IACUC, or (2) designated member review by one or more members, employed only after all voting members have been provided an opportunity to call for full-committee review. Any member of the committee can request full review of an amendment. If it is determined that amendments may undergo a DMR, the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). If it is determined that an amendment must undergo a full committee review, the FCR will be done at the regularly scheduled IACUC meetings or via teleconferencing (NIH Notice NOT-0D-06-052) if the review must be done outside of regularly scheduled IACUC meetings. Methods of telecommunications (e.g., telephone or video conferencing) are conducted under the following criteria:

• All members are given notice of the meeting.
• Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
• All members have access to the documents and the technology necessary to fully participate.
• A quorum of voting members is convened when required by PHS Policy.
• The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication).
• If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
• Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but may not be counted as votes or considered as part of the quorum.
• Written minutes of the meeting are maintained in accord with the PHS Policy, IV.E.1.b.

Approved amendments are signed by the IACUC Chairperson or designee and included as part of the approved protocol.

Major changes defined in Center policy include but are not limited to, a change in: (1) the study objective(s), (2) a surgical procedure from non-survival to survival, (3) invasiveness of a procedure or discomfort to an animal, (4) the species or the approximate number of animals used, (5) essential personnel involved in animal procedures, (6) anesthetic agent(s) or the use/withholding of analgesics (not intended to limit the clinical judgment of a veterinarian in treating individual animals), or (7) the method of euthanasia.

Amendments addressing issues not listed above are considered minor. Minor changes are also submitted on the amendment, but the IACUC chairperson at his/her discretion can approve minor changes without full committee review. Minor changes are also included as part of the approved protocol.

## c. Special Considerations for IACUC/OB Review [*Guide*, pp. 5; 27-33]

### i. Experimental and Humane Endpoints [*Guide*, pp. 27-28]

**1)** Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

The FDA does not permit death as an endpoint except for Regulatory Protocols. Humane endpoints are determined by the PI in consultation with the veterinary staff and described in detail in the animal research protocol form under section 16, Experimental Endpoint Criteria. These criteria are normally based on the information provided in section 14, Resultant Effects, if any, that the animals are expected to experience. The endpoints are provided in the protocol for review and approval by the IACUC. The Post Approval Monitoring program specifically checks to confirm that the scientific end-points being used are consistent with those in the approved protocol. If information on alternative endpoints is not available, a member of the veterinary staff is present for study procedures until endpoints are established. The results of these initial studies including the established endpoints are reported to the IACUC and incorporated as part of the study.

**2)** For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., (b) (4) studies, special monitoring, other alternatives).

In Regulatory Protocols, observation of severe signs of botulism, such as hind limb paralysis and labored breathing, especially within 48 hours with no symptoms in mice treated with control, is sufficient evidence for the presence of botulinum neurotoxin in the samples. In those instances, the mice will be euthanized.

**3)** Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

Study personnel trained in animal pain and distress observation, animal husbandry unit personnel and the veterinarian.

**ii. Unexpected Outcomes that Affect Animal Well-being** [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

The CFSAN animal research program has no protocols for the generation of Genetically Modified Animals. The Genetically Modified Animals that are utilized by the program were engineered in commercial or academic facilities and provided to CFSAN. Investigators that conduct research with GMAs are required to provide information on any special requirements for GMAs prior to protocol approval to confirm that the program can provide for any special requirements. At the current time, the GMAs in the facility have no special requirements.

**iii. Physical Restraint** [*Guide*, pp. 29-30]
*Note:* This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

**1)** Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

There are no protocols that require prolonged restraint.

**2)** Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
- the duration of confinement
- acclimation procedures
- monitoring procedures
- criteria for removing animals that do not adapt or acclimate, and
- provision of veterinary care for animals with adverse clinical consequences.

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Only temporary restraint is used. A sling is used for temporary pig restraint. The pigs are acclimated to the sling prior to procedures.

**iv. Multiple Survival Surgical Procedures** [*Guide*, p. 30]

*Note:* One survival surgical procedure followed by a non-survival procedure is not included in this category.

**1)** Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

> Conduct of multiple major survival surgical procedures is discouraged and has not been approved for prior studies or those in progress. Future requests are not anticipated.

**2)** Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

> If a study requiring multiple major survival surgeries were necessary, the protocol submitted for approval would follow the procedure described above and be required to contain a detailed scientific justification and description of procedures including, for example: (1) name and qualifications of the person(s) performing the surgery,(2) anesthesia, (3) instrument sterilization, (4) aseptic procedures, especially surgical site preparation, (5) the physical location for the procedure (surgical suite), (6) post-surgical care, (7) postoperative analgesia, and
> (8) principal investigator's discussion of possible pain or distress in animals and appropriate relief measures. The IACUC would review and discuss the protocol, consider the time allowed between procedures on the same animal, consider the additional requirement for more than routine institutional monitoring, and consult, as necessary, outside experts to reach its decision.

**v. Food and Fluid Regulation** [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)

- methods of ensuring adequate nutrition and hydration during the regulated period

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

**MOD-1**

Food restriction is a temporary, limited procedure that is required when a test substance is administered by gavage or animals are undergoing surgical procedures. Fasting is limited to 12 h for all species. There are no current or past experimental situations that have required fluid restriction.

Newly received rabbits are provided measured quantities of food that are equivalent to their normal daily intake and sufficient to maintain normal body weight and activity rather than being fed *ad libitum* for 24 h after arrival in the facility. This is done to prevent overeating and minimize the potential for digestive system problems encountered during acclimation.

**GCSL**

Short term food restriction of less than 72 hours is required when a test substance is administered intravenously, by gavage, waterborne exposure, or when fish are catheterized for blood or urine collection. There are no current nor have there been past fluid restriction requirements.

**Moffett Center**

No food or fluid restrictions are required.

Monitoring of food-restricted animals is described by protocol and carried out by contract animal husbandry personnel, the Principal Investigator, or both. Such monitoring over the course of a day may include observations for weight loss and other changes in activity or demeanor that is outside of acceptable norms. Monitoring of food-restricted fish is described by protocol and carried out by the principal investigator and/or study personnel. Food restriction in experimental fish is well within normal dietary needs of the species.

**vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances** [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

**Clinical Use** –The CFSAN animal research program uses

pharmaceutical-grade compounds for the clinical treatment of animals and to prevent or reduce/eliminate animal pain or distress. The program does not use non-pharmaceutical grade drugs for treatment of animals.

**Research Use** – Research use is defined as compounds used to accomplish a scientific goal. If available, pharmaceutical-grade compounds are preferred; but in some cases pharmaceutical grade compounds are not available. When non-pharmaceutical grade compounds are used for research purposes the PI must provide the IACUC with the following information:

- Use of the compound is in compliance with applicable national or regional regulatory guidelines
- A scientific justification is provided for use of a non-pharmaceutical grade compound
- Document that a pharmaceutical-grade compound is not available or the appropriate vehicle control is unavailable
- Document that the compound is required to generate data that is part of an ongoing study or that are comparable to previous work
- Document that the chemical properties of the compound are appropriate for the study and the route of administration
- Document preparation of the compound with the required QA for the material

**vii. Field Investigations** [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

**MOD-1 and Moffett Center**

Field investigations are not conducted

**GCSL**

Red Snapper harvested from the Gulf of Mexico are utilized for studies at the GCSL. The finfish are harvested from the Gulf of Mexico but the studies are conducted at the GCSL aquaculture facility.

**viii. Animal Reuse** [*Guide*, p. 5]

**1)** Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

The CFSAN animal protocol does not reuse animals that have been subjected to experimental procedures. Excess animals from breeding colonies or studies that have not been subjected to experimental procedures can be transferred to the training protocol for use in training procedures.

**2)** Briefly describe the types of activities currently approved that involve the reuse of individual animals.
*Note*: A list of specific protocols involving reuse of animals should be available during the site visit.

Excess animals from breeding colonies or studies that have not been subjected to experimental procedures can be transferred to the training protocol for use in training procedures.

**3)** Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
*Note*: A list of specific protocols involving reuse of animals should be available during the site visit.

Not Applicable

**2. Post-Approval Monitoring** [*Guide*, pp. 33-34]

**a.** Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

Post approval monitoring (PAM) is conducted using the Center for Food Safety and Applied Nutrition (CFSAN) Institutional Animal Care and Use Committee (IACUC) Policy for Post Approval Monitoring. The goal of the program is to review every active protocol at a minimum of once per year during the active phase of the protocol. Protocols that may require additional monitoring include but are not limited to those that are classified as (b) (4) studies or PIs that have past compliance issues, studies that have compliance issues identified through post approval monitoring, studies conducted by new PIs, and studies utilizing a new animal model or new procedures. An annual report is required for each active protocol under the CFSAN IACUC Policy on Annual Protocol Review. Protocols are approved for a maximum of three (3) years; continuation of the research is approved using the mechanism for approval of a new protocol.

**b.** Describe the process and frequency with which the IACUC/OB reviews the program of animal care and use.

**Program Review**
The animal care and use program is reviewed twice a year at six month intervals. The inspection is conducted using the checklist developed in conjunction with the 8th edition of the Guide. Every effort is made to conduct the Program Review during a regularly scheduled meeting to enhance participation of IACUC members. A member of the CFSAN Quality Assurance Staff is also invited to participate in the review.

**MOD-1 Facility Inspection**
The Chairperson and a member of the Veterinary staff accompany the other members on all inspections. Every effort is made to conduct the facility inspection during a regularly scheduled meeting to enhance participation of IACUC members. A member of the CFSAN Quality Assurance Staff is also invited to participate in the inspection.

**GCSL and Moffett Center**
Inspection of the satellite facilities is conducted by the IACUC member or alternate member representing the satellite facility accompanied by a member of the Safety or Quality Assurance staff or another investigator. In Accordance with the Assurance, satellite facilities may be exempted from inspection if the facility or facilities have no approved protocols in place or there are no (b) (4) studies during the previous 6 months. However, the satellite facilities are inspected prior to initiation of any (b) (4) studies with vertebrate animals.

**Reports**
Reports of program reviews and facilities inspections identify departures from the provisions of the Guide and the PHS Policy. Major deficiencies are distinguished from minor deficiencies. A major deficiency is "one which, consistent with this Policy [the PHS Policy], and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals." All other deficiencies are construed as minor. When deficiencies are cited, the Institutional Official is informed and a plan of action for correction is recommended. A copy of the last IACUC semiannual program review and inspections of MOD-1, GCSL and Moffett, and the schedule for correction of deficiencies are appended (Appendix 10 ).

**c.** Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.

- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

*Note:* A copy of the last report of these reviews should be included as **Appendix 10**.

The semi-annual CFSAN Animal research program review and facilities inspections are held in April and October.

**d.** If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

Not apllicable

**e.** Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

The IACUC Chairperson and Facility Manager conducted periodic, unscheduled assessments of the animal facility.

**3. Investigating and Reporting Animal Welfare Concerns** [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

The CFSAN Animal Program has a Standard Operating Procedure in place for reporting animal welfare concerns:

Title: Confidential Reporting of Inappropriate Care or Use of Animals Scope: Employees of the Center for Food Safety and Applied Nutrition (CFSAN), contract employees, and visitors to the CFSAN animal facility

Purpose: To establish procedures for reporting incidents or practices of animal care or use considered to be inhumane or detrimental to animal health

and welfare.

1. In compliance with the Animal Welfare Act Regulations (§2.31,c,4), all employees of the Center for Food Safety and Applied Nutrition (CFSAN) including contract employees, and the general public, maymake complaints concerning animal welfare within the CFSAN animal research program.

2. In compliance with Animal Welfare Act Regulations (§2.32,c,4) no employee of the Center for Food Safety and Applied Nutrition (CFSAN) including contract employees, and no IACUC member shall be discriminated against or be subject to any reprisal for making a complaint concerning animal welfare within the CFSAN animal research program.

3. Any person who observes physical or psychological wrongful or abusive treatment of an animal (e.g. hitting, taunting), or protocol noncompliance, should immediately report the complaint to the Chairperson of the CFSAN Institutional Animal Care and Use Committee (IACUC) or any other member of the CFSAN IACUC, a member of the CFSAN Veterinary staff, or the CFSAN Institutional Official. This can be done by providing a description of the complaint in person, or by providing the description anonymously. Reports should be made in writing to assure clear communication of the complaint, but may be made verbally. The complaint should include a clear and complete description of the incident or practice, the animal species involved, the location of the animals, the name(s) of the individual(s) involved (if known), and the date and time the incident occurred. The identity of all persons providing such information will remain confidential if requested by the complainant.

a. Complaints can be placed in the mailbox of the Chairperson of the CFSAN Institutional Animal Care and Use Committee (IACUC) or any other member of the CFSAN IACUC, a member of the CFSAN Veterinary staff, or the CFSAN Institutional Official.

b. Complaints can be provided through e-mail to the Chairperson of the CFSAN Institutional Animal Care and Use Committee (IACUC) or any other member of the CFSAN IACUC, a member of the CFSAN Veterinary staff, or the CFSAN Institutional Official.

c. Complaints can be communicated in person to the Chairperson of the CFSAN Institutional Animal Care and Use Committee (IACUC) or any other member of the CFSAN IACUC, a member of the CFSAN Veterinary staff, or the CFSAN Institutional Official.

4. If other than the IACUC Chairperson, the individual receiving the complaint shall immediately forward the description of the incident to the IACUC Chairperson for immediate investigation. The Chairperson shall investigate the initial complaint; anonymous complaints shall be investigated to the extent possible based on the information provided. The complaint and the information from the investigation shall be provided to the IACUC in a timely manner. This

may be done electronically, during a regularly scheduled meeting, or by convening a special meeting of the IACUC; the method of dissemination will be determined by the IACUC Chairperson.

If the complaint concerns the IACUC chairperson, the information shall be provided to the Vice Chairperson of the committee for investigation.

5. Results of the investigation and any corrective actions shall be communicated to the complainant(s) unless the complaint was received anonymously.

**4. Disaster Planning and Emergency Preparedness** [*Guide* p. 35]

Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:

- Identify those institutional components and personnel which would participate in the response.
- Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

*Note:* A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

The CFSAN animal research program has a disaster plan in place for each facility including the satellite facilities. The plan includes provisions for euthanasia and actions to prevent loss of animals due to system failures. The plan also includes excepted (essential) personnel and has been exercised in triage planning to meet investigators' needs.

## II. Animal Environment, Housing and Management

*Note:* Complete each section including, where applicable, procedures performed in farm settings, (b) (4) studies, aquatic environments, etc.

### A. Animal Environment

*Note*: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

**1. Temperature and Humidity** [*Guide*, pp. 43-45]

**a.** Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.

*Note:* If preferred, this information may be provided in a Table or additional

Appendix.

**MOD-1**

Animal rooms can be individually set for temperature and humidity. Prior to receipt of animals for an approved study, the environmental requirements (temperature, humidity, air pressure gradients, light cycle, and air exchange rate) for housing are established jointly by the Veterinary Staff, the CFSAN Research Facility Manager, and the contract managers for the AHU staff. Environmental parameters are maintained as required by the *Guide*. Animal husbandry contract personnel document the environmental requirements. The information is forwarded by the CFSAN Research Facility Manager to operations and maintenance contract personnel for establishment and stabilization of environmental conditions before animals are housed in the room selected.

A Johnson Control energy management system (Tritium) is used to set ranges and monitor temperature, humidity, as well as air flow in individual spaces. The information collected by the Tritium system is accessible to building operations and maintenance engineers at a main computer terminal and several satellite computer stations in the facility. Access to stored information and the ability to change settings is regulated at different access levels through a programmed magnetic card identifier. System failure affecting the environmental conditions of an animal room activates an alarm at the facilities computer control center. Operations and maintenance personnel are notified and dispatched to correct the problem. If the space is significantly out of established temperature or humidity parameters, and the problem cannot be resolved within a half hour of discovery, the on-call contract animal husbandry supervisor is notified so procedures to move animals can be implemented, if necessary.

Digital display panels are located throughout the return corridors for the monitoring of temperature, relative humidity and differential air pressure for the animal rooms. Instrumentation for monitoring the light cycle is available if required for a specific study. A U.S. National Institute of Standards and Technology (NIST) calibrated hand-held temperature and humidity probe is used to periodically calibrate monitoring devices. Temperature and humidity are observed and manually recorded twice per day on regular business days and once per day on weekends and holidays by animal husbandry contract personnel. The CFSAN Research Facility Manager, the veterinary staff, and PIs if requested, are notified when the temperature/humidity parameters are out of the specified range. If either or both are out of range, operations and maintenance contract personnel use diagnostic equipment to assess and correct the problem. Specifically-designated technicians operate the diagnostic devices to measure temperature, humidity, air pressure, air flow, and volume. The equipment is calibrated every six months by an independent laboratory using NIST recommended guidelines. Calibration procedures verify the measurements reported by the HVAC sensors that are displayed on computer work terminals. Additionally,

according to industry standards, the contractor performs a yearly calibration of the air flow controllers. The light timers within the animal facility are being upgraded to provide continually monitoring through the building automation system.

For conditions in an occupied animal room that are outside of established parameters, a work order is prepared and forwarded to the operations and maintenance contractor for correction as soon as possible. Unoccupied animal rooms are identified with signage on the door. Problems in unoccupied animal rooms are corrected on a lower priority schedule to assure maintenance of conditions in occupied rooms.

See Appendix 11 for a summary of heating, ventilation, and air conditioning (HVAC) systems.

**GCSL**

The wet lab (Room 132) temperature is maintained at 70˚ F. Humidity is not controlled. Temperature control is provided by a dedicated 3.5 ton Carrier™ heat pump unit. Forced air hot water heaters provide supplemental heat. Eight individual "living stream" culture units (75 gallons) can be equipped with chillers to provide cooler water temperatures for fish or experimental situations when required. Four of the eight units are interchangeable between freshwater (recirculating) and saltwater (flow through). Four units are dedicated to freshwater use. Any system failure affecting the environmental conditions of the wet lab is noted and maintenance personnel are dispatched to correct any problems. See Appendix 11 for a summary of heating, ventilation, and air conditioning (HVAC) systems.

**Moffett Center**

Animal Room 409 within the select agent suite is individually set for a temperature of 70˚ F and 30 to 70 percent humidity. Prior to receipt of animals for an approved study, the environmental requirements (temperature, humidity, air pressure gradients, and air exchange rate) for housing in Room 409 are confirmed by the animal facility staff.
Environmental parameters are maintained as required by the Guide. Animal facility staff documents the environmental requirements.
Temperature control is provided by a dedicated heat pump unit and humidity control is provided by a dedicated humidifier installed within Room 409. Temperature and humidity are observed and manually recorded twice daily by animal facility personnel. Animal Room 409 contains a computerized temperature and humidity recording device. If the temperature/humidity parameters are out of the specified range, Moffett Center maintenance personnel use diagnostic equipment to assess and correct the problem. System failure affecting the environmental conditions of an animal room activates an alarm at the facilities computer control center. The emergency power comes up in 90 seconds. A NIST calibrated hand-held temperature and

humidity probe is used to periodically calibrate the data logger. See Appendix 11 for a summary of heating, ventilation, and air conditioning (HVAC) systems.

**b.** List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
*Note:* If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

All animal species in MOD 1, out of range fluctuations are unacceptable. Animals in the affected room will be immediately transferred to another room that meets the specific requirement for the species of animals affected.

**GCSL**
Not Applicable

**c.** Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

There are no exceptions for temperature set points or environmental conditions outside the thermoneutral zone.

**2. Ventilation and Air Quality** [*Guide*, pp. 45-47]

**a.** Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

**MOD-1**
The air handling system supplies 100% fresh air to the animal facility and is separate from the system for laboratory and administrative space. The heating, ventilating and air-conditioning (HVAC) system provides air through MERV 11 high efficiency; high capacity, pleated panel filters to the animal facility at an average rate of about 10-15 air changes per hour (HVAC report-Appendix 4). The pressure differential of air within the animal facility is maintained at highest pressure in the supply-side corridors, intermediate pressure in animal rooms, and lowest pressure in return-side corridors. Airflow tubes are installed over about 60% of the doors to the animal rooms from the supply-side corridors.

They serve as continuous indicators of the direction of air flow and are monitored by the animal husbandry staff and the operations and maintenance contract personnel. Phased installation of air flow indicators over all doors is planned as funds are available. During IACUC semiannual inspections, the directional pattern of air flow within the animal facility is evaluated. Additionally, and in accord with industry standards, the operations and maintenance contractor performs a yearly calibration of the air flow controllers.

**GCSL**
The wet lab is configured for recirculated air. The additional rooms adjacent to the wet lab are configured for 90 - 100% ventilation. See Appendix 4 for a summary of heating, ventilation, and air conditioning (HVAC) systems.

**Moffett Center**
The air handling system supplies 100% fresh air to the animal facility and is separate from the system for laboratory and administrative space. The heating, ventilating and air-conditioning (HVAC) system provides HEPA-filtered air to the animal facility at an average rate of 10- 15 air changes per hour. The pressure differential of air within the animal facility is maintained at highest pressure in the animal room, and lowest pressure in the out-side corridor. An airflow tube is installed over the door to animal Room 409. It serves as a continuous indicator of the direction of air flow and is monitored by animal facility personnel. See Appendix 11 for a summary of heating, ventilation, and air conditioning (HVAC) systems.

**b.** Describe ventilation aspects of any special primary enclosures using forced ventilation.

**MOD-1**

Breeding colonies of genetically modified mice are housed in Individual Ventilated Cages purchased from Allentown Caging. The air supply to the caging and the return air are HEPA-filtered.

**GCSL and Moffett Center**

Not Applicable

**c.** If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

**MOD-1 and Moffett Center**
Recirculated air is not utilized.

**GCSL**
Air is recirculated through coarse particulate filters.

**3. Life Support Systems for Aquatic Species** [*Guide*, pp. 84-87]

**a.** Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

**MOD-1 and Moffett Center**
Not Applicable

**GCSL**
Fish are housed in standard, commercially available tanks that meet ILAR guidelines (ILAR Journal Vol. 37 No.4). Fish are housed in four 340 gallon circular fiberglass tanks with fiberglass and nylon net lids. Each unit is equipped with a water filtration system, and additional air stones. The tanks are used in recirculating configuration for maintenance of freshwater (catfish, *Ictalurus punctatus*) or recirculating/flow-through for saltwater (red snapper, *Lutjanus campechanus*) species.

Description:
• Tank dimensions: circular 60 in. diameter x 30 in. height
• Water filtration: Jacuzzi (Toronto, Canada) Laser Filter Model L225C-7. Filter media: sand. Pentair Aquaculture Sea Horse pump, ½ HP, Model DYNII – N1 - ½/340015; Flow rate = 1,800 gallons/hr. Charcoal filtration: Red Sea (Houston, TX) Ocean Clear canister filter Model 320.

**b.** Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
*Note*: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

**GCSL**
Description:
• Tank dimensions: circular 60 in. diameter x 30 in. height
• Water filtration: Jacuzzi (Toronto, Canada) Laser Filter Model L225C-7. Filter media: sand. Pentair Aquaculture Sea Horse pump, ½ HP, Model DYNII – N1 - ½/340015; Flow rate = 1,800 gallons/hr. Charcoal filtration: Red Sea (Houston, TX) Ocean Clear canister filter Model 320.

4. **Noise and Vibration** [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

**MOD-1**
Walls in the animal facility are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. The ceilings are double-layered drywall with a Cocoon® finish (a sprayable vinyl coating) and are sealed at the walls, around light fixtures and air ducts. The flooring is a sheet composition vinyl with integral coves and welded seams. There is 16 ft. distance between floors of the animal facility. Doors are metal. Sound attenuating units are installed in the supply air ductwork of the air handling equipment located in the MOD-1 mechanical rooms. There is no background noise other than the normal operating sound of the HVAC system. Efforts are made by animal husbandry, study and other personnel to minimize loud or sudden noise associated with routine procedures in the animal rooms.

**GCSL**
The walls in the fish facility are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. The ceilings consist of drop acoustic panels. The flooring is concrete with two coats of floor-grade epoxy paint (non-skid). There is no background noise other than the normal operation of the HVAC system and air/water filter/pump motors. Efforts are made by study personnel to minimize loud or sudden noise associated with routine procedures in the animal rooms. There is not any vibration in the wet laboratory. Pumps are kept on short platforms made from pvc pipes and high-density polyethylene cutting board material (for absorbing vibrations) and do not vibrate the floor.

**Moffett Center**
The walls in the mouse facility are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. The ceilings consist of dry wall coated with two coats of epoxy paint. The flooring is concrete with two coats of floor-grade epoxy paint (non-skid). There is no background noise other than the normal operating sounds of the HVAC system. Efforts are made by animal husbandry, study and other personnel to minimize loud or sudden noise associated with routine procedures in the animal rooms.

**B. Animal Housing** (all terrestrial, flighted, and aquatic species)

1. **Primary Enclosures**
*Note:* A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries,

tanks) should be included in **Appendix 13**.

**a.** Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing (b) (4) studies.

**MOD-1**
Animals are housed in commercially-available laboratory primary enclosures that comply with the recommendations provided in the Guide and the Agriculture Guide for research with agricultural animals.

Rodents are housed in standard polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops. Cages are in good condition and regularly discarded when damaged or when the transparency of the sides is impaired so that the interior cannot be easily viewed. Rodent feed is placed in the formed stainless steel wire lid and a water bottle with a sipper tube is placed in the appropriate position on the lid. Cages are set on racks so that animals can see each other through the sides.

A BCU-2000 Biocontainment (Allentown Caging, Inc.) ventilated rack with containment caging is used to house mice. The rack utilizes standard polycarbonate shoebox caging with a stainless steel wire lid and solid tops. The cages are in good condition and regularly discarded when damaged or when the transparency of the sides is impaired so that the interior cannot be easily viewed. Rodent feed is placed in the formed stainless steel wire lid and a water bottle with a screw-cap sipper tube is placed in the appropriate position on the lid. Cages are set on racks so that animals can see each other through the sides. Caging is certified on an annual basis through the Safety Team.

Individual ventilated caging is also used to house genetically modified mice with a compromised immune system. The rack utilizes standard polycarbonate shoebox caging with a stainless steel wire lid and filter tops. The cages are in good condition and regularly discarded when damaged or when the transparency of the sides is impaired so that the interior cannot be easily viewed. Rodent feed is placed in the formed stainless steel wire lid and a water bottle with a sipper tube is placed in the appropriate position on the lid. Cages are set on racks so that animals can see each other through the sides.

Rabbit cages consist of plastic enclosures, supported by a stainless steel frame, with floors designed to allow excreta to pass. Food is contained in stainless steel "J" feeders and water is provided by individual bottle with sipper

tube.

Guinea Pigs are housed in polycarbonate One Cage 2100 caging with a water holder and SSJ feeder. The cages are in good condition and regularly discarded when damaged or when the transparency of the sides is impaired so that the interior cannot be easily viewed. Rodent feed is provided in stainless steel SSJ feeders, and a water bottle with a sipper tube is placed in the appropriate position on the lid. Cages are set on racks so that animals can see each other through the sides.

Pigs are housed in a renovated quarantine room (21 sq. ft.) on the ground floor of the animal facility. The flooring is a sheet composition vinyl with integral coves and welded seams, and the walls are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. Access to the animals is provided through a break resistant, clear access panel on the front of the enclosure. Sanitizable mats are provided for added animal comfort. Water is provided by a wall mounted Rubbermaid Kane Baby Pig waterer with lixit. Feed is provided in a Rubbermaid Hold Tuf feeder mounted to the wall. The height of the feeder and waterer are adjustable.

**GCSL**

Fish are housed in standard, commercially available tanks that meet ILAR guidelines (ILAR Journal Vol. 37 No.4). Fish are housed in four 340 gallon circular fiberglass tanks with fiberglass and nylon net lids. Each unit is equipped with a water filtration system, and additional air stones. The tanks are used in recirculating configuration for maintenance of freshwater (catfish, Ictalurus punctatus) or recirculating/flow-through for saltwater (red snapper, Lutjanus campechanus) species.

Description:

• Tank dimensions: circular 60 in. diameter x 30 in. height

• Water filtration: Jacuzzi (Toronto, Canada) Laser Filter Model L225C-7. Filter media: sand. Pentair Aquaculture Sea Horse pump, ½ HP, Model DYNII – N1 - ½/340015; Flow rate = 1,800 gallons/hr. Charcoal filtration: Red Sea (Houston, TX) Ocean Clear canister filter Model 320.

**Moffett Center**

Mice are housed in commercially-available laboratory primary enclosures that comply with the recommendations provided in the Guide. Standard, disposable, polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops are used. Rodent feed is placed in the formed stainless steel wire lid and a water bottle with a sipper tube is placed in the appropriate position on the lid.

**b.** Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

There are no exceptions to the *Guide*.

**2. Environmental Enrichment, Social, and Behavioral Management** [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

**a. Environmental Enrichment**

**i.** Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

**MOD-1**
Clear polycarbonate plastic is the material of choice for caging of rodents and guinea pigs because it allows visual contact among members of the same species and maximum illumination of the interior of the primary enclosure for animal observation purposes. Rodents and guinea pigs receive sufficient bedding material for warmth and to allow for normal burrowing activities, unless the protocol dictates otherwise. Guinea pigs are provided with Guinea Pig Huts and rodents are provided with Mouse Tunnels and Mouse Igloos as privacy areas.

Rabbits are housed in plastic caging since plastic provides a warmer environment for rabbits and reduces the noise level from animal movement when compared to metal caging. Dividers can be removed to provide social housing if permitted by the protocol.

**GCSL**
Catfish, a sedentary animal, can hide under the solid portion of the tank lid in the holding tank. Small pieces of pvc pipe can be provided for additional hiding places.

**Moffett Center**
Clear polycarbonate plastic is the material of choice for mouse caging because it allows visual contact among members of the same species and maximum illumination of the interior of the primary enclosure for animal observation purposes. Rodents are housed individually or in groups, depending on their age, sex, weight, and the protocol requirements. Rodents receive sufficient bedding material for warmth and to allow for normal burrowing activities, unless the protocol dictates

otherwise.

**ii.** Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

**MOD-1**

Social animals are housed in physical contact with conspecifics as permitted by protocol and compatibility of groups. The population density of group-housed animals allows room for exercise and the expression of species-typical behavior and cognitive stimulation within the cage environment. Mice are group-housed based on age, sex, and weight following recommendations of the Guide for cage size. Female mice and compatible male mice may be segregated by sex and group-housed prior to being placed on test. Depending on study requirements, these animals may continue to be group- housed during the study. Rodents and guinea pigs are provided with sufficient bedding for burrowing, and breeding animals are provided with materials for nesting. Rabbit cages feature a removable divider to permit group housing, if appropriate.

Environmental enrichment is provided to all research animals unless contraindicated by the parameters of the study. A number of enrichment devices are available to the animals, and the enrichment devices are rotated to provide continual stimulation to the animals. The devices available by species include:

- Guinea Pigs: Guinea Pig Hut
- Pigs: Ball, Big Red Apple, Towels
- Rabbits: Dumbbells, Jingle Balls, and Big Red Apple
- Rodents: Non-edible Nylabone, Mouse Tunnels, Fast Tracs, Mouse Igloo, Nestlets

Certified food enrichment treats are also available if approved by the PI.

**GCSL**

Fish are housed communally by species and date of stocking until needed for a specific protocol/procedure. PVC piping of various sizes is also available for placement in the tanks.

**Moffett Center**

Mice are housed in physical contact with conspecifics as permitted by protocol and compatibility of groups. The population density of group-housed animals allows room for exercise and the expression of species-

typical behavior and cognitive stimulation within the cage environment. Mice are group-housed based on age, sex, and weight following recommendations of the *Guide* for cage size.

**b. Social Environment** [*Guide*, p. 64]

**i.** Describe institutional expectations or strategies for social housing of animals.

The CFSAN animal research program requires group housing of social animals unless scientifically justified in the protocol and approved by the IACUC. Individual housing of social animals must be scientifically justified in the animal research protocol and approved by the IACUC.

**ii.** Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for housing animals individually.

Scientific justification for individual housing of social animals is approved on a case by case basis. The protocol form prompts for a justification for single housing of social animals.

**iii.** Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

All individually housed animals receive environmental enrichment as described above. Rodents are housed in clear polycarbonate cages, and rabbits are housed in open front caging in close proximity to allow for visual and sensory contact. Pigs are housed in cubicles to allow for visual and sensory contact. Pigs are also provided daily human contact by the animal husbandry staff and study personnel.

**c. Enrichment, Social and Behavioral Management Program Review** [*Guide*, pp. 58, 69]

Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

Enrichment is a part of the CFSAN animal research program. Any restrictions to enrichment must be justified as part of the protocol and the restrictions are reviewed during the protocol review process. A description of animal housing is required on the protocol form as part of the description of experimental

design. A justification for single housing of social animals must be provided and is reviewed during the protocol review process.

**d. Procedural Habituation and Training of Animals** [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

**MOD-1**
Animals are provided an acclimation period prior to release for experimental procedures. During this time animals are handled by the animal husbandry staff and acclimated to their cage environment and the husbandry routine of the facility. Pigs are slowly acclimated to use of the sling prior to use in procedures.

**GCSL**
Animals are provided an acclimation period prior to release for experimental procedures. Study personnel will walk around the tanks and speak softly to allow the fish to acclimate to a person's voice.

**Moffett Center**
Habituation is minimal since mice are in the animal facility for a maximum of one week.

**e. Sheltered or Outdoor Housing** [*Guide*, pp. 54-55]

**i.** Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

Outdoor housing is not utilized for vertebrate animals.

**ii.** Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

Not Applicable

**iii.** Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

Not Applicable

**f. Naturalistic Environments** [*Guide*, p. 55]

**i.** Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

Not Applicable

**ii.** Describe how food, water, and shelter are provided.

Not Applicable

**iii.** Describe how animals are captured.

Not Applicable

## C. Animal Facility Management

### 1. Husbandry

**a. Food** [*Guide*, pp. 65-67]

**i.** List type and source of food stuffs.

**MOD-1**

Harlan Teklad, Inc., Madison, WI:
- Global 18% Protein Rodent Diet
- Irradiated Global 18% Protein Rodent Maintenance Diet
- Global Guinea Pig Diet 2040C
- Global Rabbit Diet 2030

Quality Lab Products, Inc., Elkridge, MD:
- Purina Mills Rodent Diet (certified meal, pellets)
- Certified Laboratory Diet 5065 (starter feed)
- Lab test diet with 1% Primilac 5015
- Mouse control diet 5015C

Archer Farms, Darlington, MD:
- Standard Swine Diet

**GCSL**

Phillips Feed Company, Mobile, AL
- Purina catfish pellets

Local (Dauphin Island) seafood retailer:
- Fresh or frozen shrimp and squid (food for red snapper)

**Moffett Center**

Harlan Teklad, Inc., Madison, WI:
- Global 14%, 16%, and 18% Protein Rodent Diet (standard and certified meal, pellets)

**ii.** Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

**MOD-1**
All warehouse sites used to service the MOD-1 facility are fully climate-controlled facilities that are air-conditioned not to exceed 70˚ F in the warmer months. Temperature and humidity are controlled, monitored, and recorded 24 hours a day. These records are available on request and reviewed by FDA personnel at least once a year. Chemical means of vermin control are not employed. Instead, the potential for pests is minimized through excellent sanitation and inspection procedures. In addition, a building-wide vermin control program is in effect. Warehouses are inspected on a daily basis. Information concerning the quality of products is also available by phone and/or email from the supplier's representatives.

**GCSL**
The Phillips Feed Company facility for storage of catfish food is a dedicated structure with environmentally controlled conditions and a pest management program. Fresh or frozen shrimp and squid are purchased at a Dauphin Island retail establishment.

**Moffett Center**
All warehouse sites used to service the Moffett Center are fully climate-controlled facilities that are air-conditioned not to exceed 70˚ F in the warmer months. Temperature and humidity are controlled, monitored, and recorded 24 hours a day. These records are available on request and reviewed by FDA personnel at least once a year. Chemical means of vermin control are not employed. Instead, the potential for pests is minimized through excellent sanitation and inspection procedures. In addition, a building-wide vermin control program is in effect. Warehouses

are inspected on a daily basis. Information concerning the quality of products is also available by phone and/or email from the supplier's representatives.

**iii.** Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

**MOD-1**

Preparation of custom diets is performed by commercial suppliers rather than in-house when necessary.

**GCSL and Moffett Center**

None

**iv.** Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

**MOD-1**

Pelletized feed for rodents is provided *ad libitum* by placement in the wire bar lid of a polycarbonate cage unless specified otherwise in the protocol. In some studies, chemically defined meal for rodents is provided in a holstage feeder in quantities specified in the protocol. Guinea pigs are provided *ad libitum* feed by placement in stainless steel hanging J-feeders. Feed is provided in stainless steel hoppers to rabbits in a specified amount according to an approved feeding regimen. Pigs are provided food *ad libitum* in the wall mounted trough. Chickens are provided 110 g of feed per day in stainless steel hanging feeder troughs. Feed for all animals is checked for amount and cleanliness twice daily on weekdays and once on weekends and holidays.

**GCSL**

Pelletized feed for fish is provided three times a week by placement of limited amounts directly in the water. Limited amounts of frozen shrimp and squid are thawed and provided three times a week by placement directly in the water.

**Moffett Center**

Pelletized feed for rodents is provided *ad libitum* by placement in the wire bar lid of a polycarbonate cage unless specified otherwise in the protocol. Feed is checked for amount and cleanliness twice daily on

weekdays. Animals are not present in the facility on weekends or holidays.

**v.** Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

**MOD-1**

Containers of commercial feed and dietary ingredients are inspected for breaks, stains, and pest infestation, and expiration dates are checked before being accepted by the animal husbandry staff. Certificates of Analysis for certified feeds are obtained whenappropriate and archived by the AHU, with the exception of meal diet. Certificates of analysis for meal diets are provided to the PI. All forms and labeling pertaining to the inventory of commercial feeds are reviewed for completeness by the contract staff. Labeling includes date of receipt, material name, lot number and expiration date. If autoclaved feed is required, a sterility indicator is used during the process to confirm sterility.

The "first in-first out" principle is applied such that existing feed shipments are used before newly-received shipments. Feed is used prior to either the expiration date or 6 months from the milling date. Receipt, storage and feed usage is documented. The manufacturer, receipt date, lot number, milling date, quantity received, and initials of the person receiving the feed are documented. The feed storage rooms (Rooms 2601 and 1601) are kept clean and sanitized.

Spilled feed is cleaned up immediately. The floor is mopped after feed has been dispensed into containers that are stored in animal rooms. The pest control contractor regularly inspects the feed storage room for evidence of insect and vermin infestation.

Feed containers are labeled to identify the type of feed, room number, mill date, lot number, and the date the sanitized feed container was introduced to an animal room. The animal husbandry contract staff follows all applicable SOPs for feed quality control.

**GCSL**

Date of receipt of pelletized feed is recorded. If an expiration date is not provided by a producer, an expiration date of one year from date of receipt is self-imposed. Order of use is "first in - first out." Frozen shrimp and squid used as animal feed are the same products marketed for human consumption and are required by FDA regulations (21 CFR Part 123) to have been processed according to a HACCP (Hazard Analysis Critical Control Point) plan. A HACCP plan for processed fish and

fishery products is one designed to either eliminate or control to an acceptable level those hazards to human health (e.g., microbial, chemical, pesticide, etc.) that are reasonably likely to occur in such products offered for sale in the U.S. marketplace.

**Moffett Center**

Containers of commercial feed are inspected for breaks, stains, and pest infestation, and expiration dates are checked before being accepted into the facility. Certificates of Analysis for certified feeds are obtained when appropriate and archived by the principal investigator. All forms and labeling pertaining to the inventory of commercial feeds are reviewed for completeness by the animal facility staff. If autoclaved feed is required, a sterility indicator is used during the process to confirm sterility.

The "first in-first out" principle is applied such that existing feed shipments are used before newly-received shipments. Feed is used prior to either the expiration date or 6 months from the milling date. Receipt, storage and feed usage is documented in the Feed Receipt Logbook. The manufacturer, receipt date, lot number, milling date, quantity received, and initials of the person receiving the feed are documented in the logbook.

The feed storage rooms (Rooms B100 and 411) are kept clean and sanitized. Spilled feed is cleaned up immediately. The floor is mopped after feed has been dispensed into containers that are stored in animal rooms. The pest control contractor regularly inspects the feed storage room for evidence of insect and vermin infestation.

**b. Drinking Water** [*Guide*, pp. 67-68]

**i.** Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic watering, troughs, ponds, streams).

**MOD-1**

Water is provided to all animals with the exception of pigs by bottles with sipper tubes. Water is provided to chickens through an automated watering system that utilizes an in- line carbon filter. Water is provided to the pigs using the Rubbermaid Kane baby Pig waterer with lixit.

Water is provided by the Washington Suburban Sanitary Commission from its Potomac River filtration plant. The water supply at the plant is: 1) filtered, 2) coagulated with albumin to remove sediment, 3) re-filtered, 4) chlorinated, and 5) the pH is buffered. The water supply

meets or exceeds the Federal Safe Drinking Water Act requirements.

Additional treatment of water for animals is performed on-site. Tap water is purified with a commercial, continuous-loop system by reverse osmosis and passage through an ion exchange resin bed. Prior to closed-loop tank storage, the stream flows through a section of pipe for final treatment by a UV light source. The treated water in the storage tank serves as the water supply for bottle filling stations on the supply side of cage wash. The water purification system is serviced by the manufacturer, Hydro™ Systems, through an agreement for scheduled service and next-day service on request if needed. Water lines that serve the chickens have an in- line carbon filter that is changed on a quarterly basis.

The quantity and cleanliness of the drinking water is monitored at the same time animals are being observed. Water bottles contaminated with feed or bedding, or low in content, are replaced with fresh bottles. Bottles, stoppers and sipper tubes are replaced at least twice a week. During the workweek, water bottles are filled at the water bottle filling station located on the supply-side of cage wash. On weekends, holidays, and during potential emergency situations, filled carboys on each floor are used to supply water.

Water for pigs is monitored daily and the automated watering system for chickens is checked twice per day on weekdays and once per day on weekends and holidays.

**GCSL**

An on-site freshwater well is used to supply water for freshwater fish. Flow-through saltwater is supplied from pipes coming in from the Mississippi Sound on the north side of the facility. For saltwater control holding tanks, if the salinity of the water is too low, Instant Ocean sea salt is used for adjusting the water to the correct salinity.

Saltwater is mixed with the Instant Ocean sea salt following directions on the container until the correct salinity is obtained. The water is then allowed to acclimate before fish are added to the tank.

**Moffett Center**

Water is provided to the mice by a bottle with a sipper tube. Water is provided by the Metropolitan Water Reclamation District of Greater Chicago from the Lake Michigan filtration plant. The water supply meets or exceeds the Federal Safe Drinking Water Act requirements. The quantity and cleanliness of the drinking water is monitored at the same

time animals are being observed. Water bottles contaminated with feed or bedding, or low in content, are replaced with fresh bottles.

**ii.** Describe methods of quality control, including monitoring for contaminants.

**MOD-1**
None

**GCSL**
Water quality for freshwater fish is standardized by recirculating filtration. Water quality parameters of temperature and pH are monitored daily, while nitrate, nitrite, total ammonia, alkalinity, hardness are recorded weekly when fish are first introduced to the holding tanks; thereafter, the water quality parameters are monitored as needed. Saltwater fish tanks are monitored daily for temperature, salinity, pH, and dissolved oxygen.

**Moffett Center**
None

**iii.** If automatic water delivery systems are used, describe how they are maintained and sanitized.

Not Applicable

**c. Bedding and Nesting Materials** [*Guide*, pp. 68-69]

**i.** Describe type(s) and how used for various species.

**MOD-1**
Commercial bedding is received and stored in Room G602 until use in cage preparation. Harlan Teklad Tek-Fresh bedding is routinely used as contact bedding for rodents and guinea pigs. ALPHA-Dri™ is routinely used for the containment caging used for (b) (4) studies. Studies can request specific bedding that will be reviewed and approved by the veterinary staff and the IACUC. Sufficient bedding is used to keep animals dry between cage changes. Clean cages with fresh bedding are provided at least once per week; with the exception of individual ventilated caging which may only be changed once per week. Any cage found to be flooded or excessively wet is changed as soon as possible. The condition of the bedding is monitored at the same time animals are observed.
Non-contact bedding is placed in excreta pans beneath rabbit cages. Pigs are provided with soft mats that can be sanitized. Commercial nesting materials are provided for mice breeding colonies.

**GCSL**
Not Applicable

**Moffett Center**
Most contact bedding used in shoebox cages for mice is heat- treated hardwood chips (Certified Harlan Sani Chip or equivalent). A punched paper product (OMEGA-dri certified bedding, Harlan TEK-FRESH bedding, or equivalent) may also be used if specified by the protocol. Sufficient bedding is used to keep animals dry for the duration of the study. Due to the short nature of the studies, cage changes are not routinely conducted. However, a cage found to be flooded or excessively wet is changed as soon as possible.
The condition of the bedding is monitored at the same time animals are observed.

**ii.** Describe bulk bedding storage facilities, if applicable, including vermin control measures.

**MOD-1**
Bedding material is stored on pallets in Room G602 that is climate-controlled and monitored for temperature and relative humidity.
When transferred, each paper bale or bag of bedding material is sprayed with a disinfectant to decontaminate the outside. Bedding is transferred into cages and the cage units are assembled in room G701. A contract integrated pest management program monitors for potential pest problems in this area. Sticky traps are used to check for insects. Contract animal husbandry personnel check for evidence of pests daily.

**GCSL**

Not Applicable

**Moffett Center**

Bedding material is stored in Rooms B100 and 411 that are climate-controlled. When transferred, each paper bale or bag of bedding material is sprayed with a disinfectant to decontaminate the outside. Bedding is transferred into cages and the cage units are assembled in Room 411. A contract integrated pest management program monitors for potential pest problems in this area. Sticky traps are used to check for insects. Animal facility staff checks for evidence of pests daily.

**iii.** Describe quality control procedures, including monitoring for contaminants.

**MOD-1**

Random samples of contact bedding are analyzed by the manufacturer for yeast, molds, pathogenic fungi, *Salmonella* spp., coliforms, PCB's, PCP's, organophosphate pesticides, organochlorine pesticides, and heavy metal contamination. Upon receipt, each bag is examined for tears, signs of stains or infestation by pests. Each bag or bale is labeled with the date of receipt, lot number, and any other pertinent information. If autoclaved bedding is required, a sterility indicator is used during the process to confirm sterility.

**GCSL**

Not Applicable

**Moffett Center**

Upon receipt, each bag is examined for tears, signs of stains or infestation by pests. Each bag or bale is labeled with the date of receipt, manufacturer, lot number, and any other pertinent information. If autoclaved bedding is required, a sterility indicator is used during the process to confirm sterility.

**d. Miscellaneous Animal Care and Use Equipment**

**i.** Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

**MOD-1 and Moffett Center**
Not Applicable

**GSCL**
Red snapper are obtained from the Gulf of Mexico. A 45' Sea Chaser with twin 150 HP Yamaha motors is used as the collection/transport vehicle. Our transport tank is placed on the boat and used as a flow-through tank. The top is placed on the tank to secure the red snapper. The water is at ambient temperature.

**ii.** Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure

sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

**MOD-1**
Transport cages and carts used for transporting animals are sanitized after each use. Carts used for transporting clean cages, feed, and bedding are sanitized after each use unless they are used solely in clean and sanitized areas. Sanitizing solutions are prepared from Quatricide PV 15™, a quaternary ammonium germicidal detergent manufactured by Pharmacal.
Other equipment items include: six (6) Lab Product waste management stations, Class II-A biological safety cabinets, three (3) floor buffer machines (one for each floor) , three (3) NuAire Animal Bedding Disposal Units, three (3) NuAire Class II Type A/B3 Biological Safety Cabinets, four (4) NuAire Class II Type A2 Safety Cabinets, two (2) Animal Transfer Stations, and three (3)Fume Hoods.

**GCSL**
A high pressure water sprayer, a floor scrubber, and a wet/dry vacuum cleaner are appropriately sanitized and dried after each use.

**Moffett Center**
None

**e. Sanitation** [*Guide*, pp. 69-73]

**i. Bedding/Substrate Change**

**1)** Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

**MOD-1**
Contact bedding used for rodents in solid bottom micro-isolate caging is changed twice per week. Contact bedding used for rodents in solid bottom individually ventilated is changed once per week. Contact bedding used in solid bottom caging for guinea pigs is changed three times per week. Pan liners used as non-contact bedding for rabbit raised floor caging are changed three times per week. The mats used as contact bedding for pigs are cleaned daily and sanitized monthly.

**GCSL**
None

**Moffett Center**
Due to the short nature of the studies, cage change are not routinely conducted.

**2)** Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used to justify those exceptions.

Not Applicable

**3)** Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

**MOD-1**

Rodent and guinea pig cages containing soiled bedding are transported on racks by way of a return corridor to cage wash room G215. Soiled bedding is disposed of in a Nu-Air Labgard Class I-Animal Bedding Disposal Cabinet. Non-contaminated, bagged and sealed waste is transported to a dumpster outside the building. Bedding and cages associated with ABSL-2 and higher studies are double-bagged in the animal room at the time of changing and autoclaved intact prior to removal of the bedding and other cage contents.

Clean bedding is manually placed into the cages in Room G701 on the supply side of cage wash. The bedded cages are maintained in a transient cage staging area on the second floor and subsequently taken directly to the animal rooms for replacement that day or within the next 48 hours.

Pan liners from (b) (4) studies are removed on the return side of cage wash, and clean liners are placed in the pans on the supply side of cage wash. Pan liners from (b) (4) studies are treated and disposed of as biohazardous waste.

**GCSL**

Not Applicable

**Moffett Center**

Soiled single use disposable cages are double-bagged in a laminar flow, HEPA-filtered containment cabinet located in the animal procedure room (Rm 114) and autoclaved intact prior to disposal.

**ii. Cleaning and Disinfection of the Micro- and Macro-Environments**

*Note:* A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

**1)** Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

There are no exceptions to the *Guide*

**2)** Assessing the Effectiveness of Sanitation and Mechanical Washer Function

**a)** Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

**MOD-1**

Tunnel washer and rack washer temperatures are monitored with Tri-temp Tape placed on cages/racks two times a day (morning and afternoon). Temp Tapes show that a water temperature of 140-180˚ F has been reached during the cage processing cycle. Tri-temp Tapes are kept in a logbook. In addition, rack washers are monitored by computer printout and twice a day (morning and afternoon) with Tri-temp Tape. The tunnel washers provide a digital display of all wash/rinse temperatures and the final rinse cycle temperature is recorded twice a day. An in-house microbiological surveillance program is utilized to monitor the effectiveness of the sanitation procedures. A log is kept to document the results. An environmental monitoring program is in place.

**GCSL**

Sanitation effectiveness of fish tanks is monitored by visual inspection.

**Moffett Center**

Dish washer temperatures are monitored with Tri-temp Tape placed on cages/racks during each use. Temp Tapes show that a water temperature of 140-180˚ F has been reached during the cage processing cycle. Tri-temp tapes are kept in a logbook.

**b)** Describe preventive maintenance programs for mechanical washers.

Preventive maintenance for mechanical washers is provided by American Medlab Services, Inc. on a quarterly basis. An example of a preventive maintenance worksheet is as follows:

- Check with customer for any washer problems
- Check over-all condition of unit (hardware, wiring, etc.)
- Clean & refill oil lubricator - (if applicable)
- Open and inspect condition of solenoid valves
- Open and inspect traps - if applicable
- Operate door, clean, and lubricate if necessary
- Inspect all filters
- Inspect twirler bearings - delrins, axles & bolts, etc.
- Inspect header assemblies - clean & flush spindle tips & debris trays
- Check water level controls
- Start unit, check operation in all cycles
- Check operation of door safety switch
- Inspect unit for leaks - water, steam, air, etc.
- Check unit's water temperature with lag meter
- Check operation of butterfly valves and air motors
- Check compartment and panel lights, replace if needed
- Check pump pressure, if abnormal remove and clean strainer
- Check dryer assembly operation - if applicable

Lubricate conveyor belt bearings - if applicable

**f. Conventional Waste Disposal** [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

**i.** Soiled bedding and refuse.

**MOD-1**

Soiled bedding and refuse free of hazardous material is disposed of in the general waste stream. Soiled bedding and refuse that has been decontaminated by autoclaving is disposed of in the general waste stream. Nonhazardous and autoclaved bedding is collected into plastic trash bags at a cage dumping station that provides directional air flow and HEPA filtration. The bags are placed in dumpsters that are serviced by a licensed contractor. Dumping stations are available on the return side of cage wash in the designated dumping area, Room 2810. Dumpsters are serviced by a licensed contractor. Soiled bedding and refuse that cannot be disposed of in the general waste stream due to a hazard associated with a specific study is removed by a licensed contractor coordinated by

the Safety Team.

**GCSL**

Refuse free of hazardous materials is placed in dumpsters that are serviced by a licensed contractor.

**Moffett Center**

Nonhazardous bedding and waste and autoclaved biohazardous waste is collected into plastic trash bags at a waste management station equipped with directional air flow away from the operator and HEPA filtration. The bags are placed in dumpsters that are serviced by a licensed contractor.

**ii.** Animal carcasses.

**MOD-1**

Animal carcasses are double-bagged in leak-proof plastic bags that are boxed and held in a designated walk-in freezer on the ground floor of MOD-1 (Room G224a) until disposal. Boxes are removed up by a licensed medical waste contractor and transported to an approved incinerator.

**GCSL**

Animal carcasses are incinerated in Room 110.

**Moffett Center**

Animal carcasses are placed in leak-proof plastic bags that are boxed and held in a designated chest freezer in Room 411 until disposal. Animal carcasses from (b) (4) studies are transferred to leak-proof containers within a biosafety cabinet, the containers are sealed and disinfected, and autoclaved prior to disposal. Boxes are picked up by a licensed medical waste contractor and transported to an approved incinerator.

**g.** **Pest Control** [*Guide*, p. 74]

**i.** Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and

- who oversees the program, monitors devices, and/or applies the agent(s).

**MOD-1**
A regularly scheduled integrated pest management program for monitoring and control of vermin and insect pests is implemented under contract by R and T Pest services. The FDA COR for the contract is the Muirkirk Road Complex Facilities Manager. CFSAN provides technical support and monitoring to the FDA COR through the Attending Veterinarian. CFSAN and animal husbandry contract personnel participate in the program by reporting the appearance of any pests in the facility. Monitoring is conducted primarily with use of insect glue boards and rodent traps. In addition, a significant part of the program involves the prevention of pests in the animal facility. This is accomplished by surface sanitization of the outside of any materials brought into the animal facility, and immediate unpacking and disposal of corrugated cardboard or other packing materials. Equipment and caging is thoroughly cleaned and sanitized. Areas are inspected for penetrations and preventive caulking is performed. A pest management log is maintained in the office of the Attending Veterinarian.

**GCSL**
The facility maintains an integrated pest management program for monitoring and control of vermin and insect pests. It is implemented under a contract with Cook's Pest Control. Pesticide sprays are not used in animal rooms. Pest control is achieved through maintenance of clean conditions within the animal facility augmented with pesticide treatment of the space surrounding the animal use area.

**Moffett Center**
The facility maintains an integrated pest management program. Pesticide sprays are not used in animal rooms. Pest control is achieved through maintenance of clean conditions within the animal facility augmented with pesticide treatment of the space surrounding the animal use area.

**ii.** Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

Not Applicable

**iii.** Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

**MOD-1, GCSL and Moffett Center**

Pesticides are not used within the animal facility.

**h. Weekend and Holiday Animal Care** [*Guide*, pp. 74-75]

**i.** Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

**MOD-1**
Emergency contact information is posted in the administrative office (Room G213) and the Floor Supervisor Offices (Rooms 1604 and 2606) listing the veterinarians, investigators, and other personnel who are to be contacted for animal health problems and/or in an emergency. Emergency contact information specific to each study is also posted on the animal room door(s) housing the study animals. The veterinarian assigned to MOD-1 provides weekend and holiday care. Animal observations and parameters are conducted by regular animal husbandry staff once per day on weekends and holidays. If an animal's condition appears abnormal, a veterinarian is contacted by phone; staff veterinarians are provided cell phones by CFSAN to permit 24/7/365 contact. The principal investigator for the study is also contacted. The reporting animal technician describes the condition and a member of the veterinary staff provides immediate verbal instructions, determines if the animal requires further examination, and provides appropriate treatment as soon as possible. Written instructions for follow-up care are also provided.
Contract animal husbandry management personnel are equipped with cell phones to permit contact 24 hours a day for emergencies and other special needs.

**GCSL**
Names and telephone numbers of emergency contact personnel are posted at the entrance of the fish housing area (Room 118). If environmental conditions or fish appear abnormal, the Principal Investigator or biologist is contacted by telephone. Remedial actions are performed at the direction of the Principal Investigator or biologist who proceeds to the facility to correct the aberrant condition. The CFSAN veterinarian are contacted when additional information on animal care is required.

**Moffett Center**
Names and telephone numbers of emergency contact personnel are posted at the entrance door of Room 409. If environmental conditions or mice appear abnormal, the Principal Investigator is contacted by telephone.

Remedial actions are performed at the direction of the Principal Investigator who proceeds to the facility to correct the aberrant condition. The CFSAN veterinary staff and/or consulting veterinarian are contacted when additional information on animal care is required.

**ii.** Indicate qualifications of weekend/holiday staff if not regular staff.

Weekend/holiday staff are regular staff.

**iii.** Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

**MOD-1**
Emergency contact information is posted in the animal care office (Room G213) and the Floor Supervisor Offices (Rooms 1604 and 2606), listing the veterinarians, principal investigators, and other personnel who are to be contacted for animal health problems and/or in an emergency. Emergency contact information specific to each study is also posted on the animal room door(s) housing the study animals. The veterinary staff is provided with government issued cell phones to provide 24/7/365 day access. Contract animal husbandry management l are equipped with cell phones to permit contact 24 hours a day for emergencies and other special needs.

**GCSL**
Names and telephone numbers of emergency contact personnel are posted at the entrance of the fish housing area (Room 118). If environmental conditions or fish appear abnormal, the Principal Investigator or biologist is contacted by telephone.

**Moffett Center**
Names and telephone numbers of emergency contact personnel are posted at the entrance door of Room 409. If environmental conditions or mice appear abnormal, the Principal Investigator is contacted by telephone.

**2. Population Management** [*Guide*, pp. 75-77]

**a. Identification**
Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

**MOD-1**

All animals are identified by cage cards containing protocol number, investigator name and phone number, species, strain, vendor, date received, sex, weight, age or date of birth, room number, and number of animals per cage. In addition to the cage card, tattoos may be used to identify rabbits. Rodents may receive ear tags and/or tattooing in addition to their cage card if specified by protocol. Mice can also be identified with unique tail markings made with an indelible marker. Pigs will also be identified by ear tags.

**GCSL**
Fish are identified on data sheets attached to each of the occupied Living Stream tanks.

**Moffett Center**

All animals are identified by cage cards containing protocol number, investigator name and phone number, species, strain, vendor, date received, sex, age or date of birth, weight, room number, and number of animals per cage. Mice can also be identified with unique tail markings made with an indelible marker.

**b. Breeding, Genetics, and Nomenclature**

**i.** Describe the program for advising investigators on the selection of animals based on genetic characteristics.

**MOD-1, GCSL and Moffett Center**

If genetic characteristics of an animal model are an issue, the investigator is encouraged to consult with the veterinarian during study development. Since the genetic characteristics of most animals used in food and cosmetics safety research are established, most investigators are aware of the most appropriate models to use by species and strain.

**ii.** Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and substrain or the genetic background of all animals used in a study.

**MOD-1, GCSL and Moffett Center**

The veterinarian assists the investigator with the appropriate nomenclature, when requested.

**iii.** Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including

recordkeeping practices (*Guide*, pp. 75-76).

The veterinarian assists the investigator with the management techniques used to assess and maintain genetic variability and authenticity.

GCSL – Not Applicable

**iv.** For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

The CFSAN animal research program does not generate novel genotypes.

## III. Veterinary Care [*Guide*, pp. 105-132]

*Note:* Complete each section, including, where applicable, procedures performed in farm settings, (b) (4) studies, aquatic environments, etc.

### A. Animal Procurement and Transportation [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

#### 1. Animal Procurement

Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

**MOD-1**

The veterinary staff approves all animal orders, and the animals are ordered through a centralized animal ordering procedure to ensure that only animals for approved protocols from acceptable vendors are procured. Investigators are encouraged to procure animals from approved commercial vendors who have an active health monitoring system in place for the conduct of routine periodic health assessments and disease surveillance. The veterinary staff evaluates the specific source or originating facility with corresponding health surveillance results at the time the animal order is placed or obtains appropriate information prior to delivery of the animals to the facility.

Specific Pathogen Free (SPF) animals are preferentially used. Animals obtained from non-commercial sources (e.g. academia) must have a health

certificate from the facility approved by the Attending Veterinarian.

Investigators are encouraged to discuss use animals from non-commercial sources with the veterinary staff during the development of the protocol.

Animals from non-commercial sources may require quarantine and additional testing prior to release for research purposes. Health status of animals procured from other sources is assessed through use of commercial diagnostic services.

In situations where animals from colonies containing undesirable microbiological agents must be acquired to fulfill specific research requirements, appropriate measures are implemented to ensurecontainment and minimize the potential for cross-contamination within the facility. The specific measures are determined by the PI and the veterinary staff.

**GCSL**

Freshwater fish (catfish, Ictalurus punctatus) are procured from local (south and central Alabama) catfish farms. The Principal Investigator or study biologist assesses the quality of procured fish on-site (at the farm). The fish are observed for general appearance, health condition, and behavior.

Criteria for rejection of fish from a vendor include malformation and/or obvious disease condition(s) or aberrant behavior. Saltwater fish (red snapper, Lutjanus campechanus) are collected directly from the Gulf of Mexico. The quality of collected fish is assessed at the point of capture by the Principal Investigator or study biologists. Fish are observed for general appearance, health condition, and behavior. Criteria for rejection of saltwater fish are the same as those for freshwater fish.

**Moffett Center**

Mice are procured from approved commercial vendors who have an active health monitoring system in place for the conduct of routine periodic health assessments and disease surveillance. The veterinary staff evaluates the specific source or originating facility with corresponding health surveillance results at the time the animal order is placed or obtains appropriate information prior to delivery of the animals to the facility. Specific Pathogen Free (SPF) animals are preferentially used. Animals determined to have health problems or infected with undesirable microbiological agents are generally not allowed into the facility.

## 2. Transportation of Animals

Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

**MOD-1**

Animals are transported in an approved primary container with provisions for food and water in a vendor's climate-controlled vehicle from the origin of transport directly to MOD-1. Entrance to the MOD-1 facility is controlled by a manned guard station. The guard station is informed when an animal delivery is expected, and the guard on duty notifies the animal husbandry unit (AHU) when the animal shipment has arrived. The vendor is directed to a secured loading dock dedicated to receiving animals for the research program. The loading dock is opened by a member of the AHU staff and the vendor truck containing the animals is driven into the enclosed loading dock. The animals are unloaded, the order is confirmed as correct by a member of the AHU staff, and the integrity of the shipping containers is determined before the order is accepted. If there are problems with the order or the shipping containers the PI and/or member of the veterinary staff is contacted to determine final disposition of the animals. The shipping containers of accepted orders are treated with disinfectant and then placed inside stainless steel transport containers or flatbed carts and moved through the return side of the animal facility into the assigned acclimation room(s). Animals are placed in prepared caging in the acclimation rooms.

**GCSL**

Freshwater fish are transported by pick-up truck in a baffled 150-gallon tank. The tank is covered during transport and water is oxygenated by a diffusion block attached to an air compressor. Fish are netted for transfer between transport tanks and holding tanks. Saltwater fish are transported by boat in a baffled 150-gallon tank. The water is oxygenated by a continuous flow-through of saltwater into the baffled tank via a pump.

**Moffett Center**

Animals are transported in an approved primary container with provisions for food and water in a vendor's climate-controlled vehicle from the origin of

transport directly to the Moffett Center. In some cases, vendors may ship animals by air to a regional airport, where they are transported from the airport to the Moffett Center by a commercial delivery service.

## B. Preventive Medicine

### 1. Animal Biosecurity [*Guide*, pp. 109-110]

**a.** Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

**MOD-1**

Animals are normally procured only from approved commercial vendors or academic institutions that have an active health monitoring system in place for the conduct of routine periodic health assessments and disease surveillance. The veterinary staff evaluates the specific source or originating facility with corresponding health surveillance results at the time the animal order is placed or obtains appropriate information prior to delivery of the animals to the facility. Health status of animals procured from other sources is assessed after arrival through use of commercial diagnostic services.

The CFSAN animal research program has an active health surveillance program. For rodents, a comprehensive serology panel is conducted by IDEXX RADIL on a quarterly basis, and testing for endoparasites and ectoparasites is conducted at intervals determined by the veterinary staff. Pigs are maintained in the facility for such as short period of time that health is based on the certificates obtained from the vendors. Rabbits are obtained from a commercial vendor and observed for indications of infectious disease. Blood samples from control animals are available for analysis if deemed necessary by the veterinary staff.

**GCSL and Moffett Center**

Not Applicable

**b.** Describe methods used to control, contain, or eliminate infectious agents.

**MOD-1**
Investigators are encouraged to obtain research animals from commercial vendors with active surveillance programs. However, if animals with a known

pathogen must be acquired to fulfill research requirements, appropriate measures are implemented to ensure containment and minimize the potential for cross-contamination of the remainder of the colony.

Biosafety Level 2 (BSL-2) procedures are used for husbandry of all animals containing known pathogens that are maintained in the general housing area of the vivarium. Animal room doors are posted with the universal biohazard symbol and the name(s) of the infectious agents.
PPE for work in these rooms includes scrub clothing, a lab coat or water resistant coverall, double shoe covers, and double gloves. Lab coats/water resistant coverall, outer shoe cover, and gloves are disposed of in the animal room. Animal rooms are exited through the return corridor. PPE is replaced in the locker room prior to entering the supply side of the vivarium. Soiled animal caging including bedding, remaining feed, water and water bottles and enrichment devices are placed in biohazard bags and autoclaved on the return side of the cage washing facility.
In rare cases where animals harbor a pathogen of high concern (e.g. mouse norovirus), the animals are housed and research conducted in quarantine cubicles maintained on the ground floor within the vivarium but separate from the general housing area of the facility.

**GCSL**
Fish are observed daily. Disease conditions are identified and fish manifesting disease are isolated in separate tanks. Disease control is affected by euthanasia of diseased fish and sanitation of tanks that contained those fish.

**Moffett**
Only Specific Pathogen Free (SPF) mice from commercial vendors are utilized for studies.

2. **Quarantine and Stabilization** [*Guide*, pp. 110-111]

   **a.** Describe the initial animal evaluation procedures for each species.

**MOD-1**

The animal husbandry contractor is notified first of the arrival of a shipment of animals. In turn, animal husbandry personnel notify a veterinarian and the study Principal Investigator. Shipping cartons are examined and accompanying documentation is reviewed for consistency with the original order. Animals are unpacked by animal technicians and observed for abnormalities by AHU personnel and a member of the veterinary staff. If abnormalities are observed, they are recorded on an Animal Observation Notification Report Form for the veterinarian to evaluate. The CFSAN Animal

Receipt and Health Certification Forms are completed for each shipment. Shipping cartons are saved for the veterinarian to evaluate the integrity of the cartons, the availability of food and water, and the bedding material used.

Animals are held in acclimation for a period specified in the approved protocol prior to release for study. The animals are observed for abnormalities and weight gain during this acclimation period.

Abnormalities are reported to the veterinary staff and the Principal Investigator.

**GCSL**

Fish are picked up at the fish farm or collected by boat in the Gulf of Mexico and transported to the GCSL fish holding area (Room 118). They are transferred by netting to holding tanks containing freshwater or saltwater, as appropriate. The fish are observed for any signs of disease or aberrant behavior.

**Moffett Center**

Mice are observed for any abnormalities by the PI or animal research staff upon arrival. Animals are held in acclimation for a period specified in the approved protocol prior to release for study. The animals are observed for abnormalities during this acclimation period, and any abnormalities are reported to the PI and veterinary staff.

**b.** Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

**MOD-1**

Random source animals are not used at the MOD-1 facility. A quarantine room is located on the ground floor of the facility within the animal facility but outside of the general housing area. The quarantine rooms are maintained under negative pressure and each room is individually exhausted.

A serological workup is not routinely performed; therefore, the housing period before release of animals to a study is considered an acclimation rather than a quarantine period. Husbandry and observations are conducted in quarantine rooms after such tasks are completed in active study rooms.

PPE for acclimation rooms includes scrubs and a lab coat or water-resistant coverall, double shoe covers and double gloves, additional PPE may be required due to the health status of the animals. Information for additional PPE is communicated to the AHU personnel in writing and is posted on the acclimation room doors. The traffic pattern for an acclimation room consists of entry from the supply side corridor and exit through the return side corridor to the locker room where a protective clothing change occurs.

The veterinarian may authorize quarantine in place of acclimation or during the course of a study if professional judgment determines that quarantine is necessary to isolate an animal or group of animals from other animals in the facility. Quarantine procedures may include: (1) movement of the animals to quarantine room(s) (2) use of additional personal protective clothing in the designated room when needed, (3) limiting access to the housing room. The veterinary staff may authorize diagnostic tests to be performed by a commercial diagnostic laboratory to confirm health status of the animal(s) during the initial quarantine period. If the animals are determined to have a potentially contagious disease, they are maintained under quarantine until the condition is resolved.

**GCSL**

Fish manifesting disease are isolated in separate tanks. If the disease condition persists, the animals are euthanized and incinerated. New fish are placed in separate holding tanks according to species and date of acquisition.

**Moffett Center**

Random source animals are not used.

**c.** Describe the required/recommended stabilization period for each species.

**MOD-1**

A one week stabilization period is preferred and routine for all species, although some protocols specify shorter acclimation periods. An abbreviated stabilization period must be justified in the protocol. Reduced acclimation periods must be approved by the IACUC as part of the protocol review process. A stabilization period of less than 24 hours is not permitted unless animals are to be euthanized shortly after receipt for tissue harvest.

**GCSL**

After acquisition and transport to the fish holding area (Room 118), fish are allowed to acclimate/stabilize for seven (7) days before initiation of use in research protocols.

**Moffett Center**

A 24 hour stabilization period is approved for studies conducted in the Moffett Center Animal Facility.

**3. Separation by Health Status and Species** [*Guide*, pp. 111-112]

**a.** Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

**MOD-1**

As a general rule, animals are separated by protocol, shipment, source, species and strain into separate animal rooms. In some situations, an ongoing protocol receiving multiple shipments of the same animals from the same source and of the same health status may be housed in the same room after they have undergone an acclimation period in a separate housing room.

**GCSL**

Fish are separated by date of collection, species, health status, and by protocol into separate holding tanks.

**Moffett Center**

Studies at the Moffett Center Animal Facility utilize a single animal species from a single source.

**b.** Describe situations where multiple species may be housed in the same room, area, or enclosure.

**MOD-1**

Multiple species are not housed in the same room.

**GCSL**

Multiple species are not housed in the same tank.

**Moffett Center**

Moffett center is a mouse only facility.

**c.** Describe isolation procedures and related facilities for animals.

**MOD-1**
Animals are separated by species, strain, and health status into separate housing rooms. In some situations, an ongoing protocol receiving multiple shipments of the same animals from the same source and of the same health status may be housed in the same room.
Different shipments housed in the same room are placed on separate racks.

**GCSL**
Fish are separated by date of collection, species, health status, and by protocol into separate holding tanks.

**Moffett Center**
Studies at the Moffett Center Animal Facility utilize a single animal species from a single source.

## C. Clinical Care and Management [*Guide*, pp. 112-115]

### 1. Surveillance, Diagnosis, Treatment and Control of Disease [*Guide*, pp. 112-113]

**a.** Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:
- the observers' training for this responsibility
- method(s) for reporting observations (written or verbal)
- method(s) for ensuring that reported cases are appropriately managed in a timely manner.

**MOD-1**
AALAS-certified contract animal husbandry technicians observe animals twice a day, morning and afternoon, on workdays, and once a day on weekends and holidays. Visual observations include the health of animals and an inventory of the number of animals present. Entries are made on the Daily Animal Room Check List (DARC Form, Animal Husbandry Unit Form F-001). The floor leader verifies that recorded information is correct. The veterinarian observes the animals as necessary and during clinical rounds, and receives health status updates through communication with the animal husbandry personnel and the Principal Investigator. Abnormal health observations are reported expeditiously to the contract floor supervisor and the information is entered on the Daily Animal Room Check List and on the Animal Observation Notification Report Form (F-002). The animal husbandry staff floor leader informs the PI and the

veterinarian of any abnormalities in writing normally via email.

Once the veterinary staff is notified, they evaluate the situation and use professional judgement to determine response time. Results of the evaluation and instructions for treatment are recorded on the F-002 Form. These forms remain with the animal until the situation has been resolved. The original form is provided to the principal investigator and a copy retained in the AHU files.

**GCSL**
Fish are observed daily and verbal reports are provided to the Principal Investigator on the condition of fish and the fish holding area.

**Moffett Center**
Mice are observed daily and verbal reports are provided to the Principal Investigator on their condition.

**b.** Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

**MOD-1**
If an animal appears injured or ill during the daily observations, the cage housing the animal is marked with a red cage card. The principal investigator and a member of the veterinary staff are contacted by the animal care staff via e-mail or phone. The PI in consultation with the veterinary staff decides on disposition of the animal.

**GCSL and Moffett Center**
The animal care staff at the GCSL and the Moffett Center is the research staff.

**c.** Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

**MOD-1**

Preventive medicine programs for all species consist of monitoring the vendors' health reports and ordering only from approved vendors, observing animals daily by the caretakers, and conducting regularly scheduled rounds by the veterinarian. The CFSAN animal research program has an active health surveillance program utilizing sentinel animals for rodents. Pigs and rabbits serve as their own sentinels. A comprehensive serology panel is

conducted by IDEXX RADIL on a quarterly basis, and testing for endoparasites and ectoparasites is conducted at intervals determined by the veterinary staff. Rodent, guinea pig, and rabbit teeth and nails are monitored and trimmed as needed.

**GCSL**

Preventive medicine programs for finfish consist of daily monitoring for aberrant behavior.

**Moffett Center**

Preventive medicine programs for mice consist of monitoring the vendors' health reports and ordering only from approved vendors and by observing the animals daily.

**2. Emergency Care** [*Guide*, p. 114]

**a.** Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

**MOD-1**
The MOD-1 facility has one full time veterinarian that provides continuous care during and outside of regular work hours. The veterinarian is provided a government issued cell phone for continuous contact with the animal facility.

**GCSL**
Names and telephone numbers of emergency contact personnel are posted at the entrance of the fish housing area (Room 118). If environmental conditions or fish appear abnormal, the Principal Investigator or biologist is contacted by telephone. Remedial actions are performed either at the direction of the Principal Investigator or biologist who proceeds to the facility to correct the aberrant condition. The CFSAN veterinary staff are contacted when the choice of a proper corrective action is in question.

**Moffett Center**
Names and telephone numbers of emergency contact personnel are posted at the entrance door of Room 409. If environmental conditions or mice appear abnormal, the Principal Investigator is contacted by telephone. Remedial actions are performed at the direction of the principal investigator who

proceeds to the facility to correct the aberrant condition. The CFSAN veterinary staff and/or consulting veterinarian are contacted when the choice of a proper corrective action is in question.

**b.** Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

The Attending Veterinarian has authority to treat all animals.

**3. Clinical Record Keeping** [*Guide*, p. 115]

**a**. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

**MOD-1**

Complete individual animal records are maintained for pigs and rabbits. A health record is maintained for individual rodents identified with an abnormality or undergoing surgical procedures. Records on individual study animals are kept in the primary animal room during the study and can be accessed by the veterinary staff and IACUC at any time during the active study. Reports to the records can be made by the animal husbandry staff, the veterinarians, the Principal Investigator, and personnel approved for work on the specific study. The records are transferred to the principal investigator when the animal(s) are euthanized or at the conclusion of the study. The Attending Veterinarian reviews all records for sick animals.

**GCSL and Moffett Center**

Not Applicable

**b.** Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

**MOD-1**

Records on individual study animals are kept in the primary animal room during the study and can be accessed by the veterinary staff and IACUC at any time during the active study. The records are transferred to the principal investigator

when the animal(s) are euthanized or at the conclusion of the study.

**GCSL and Moffett Center**

Not Applicable

**c.** Describe the role of the Attending Veterinarian in recordkeeping.

The Attending Veterinarian reviews all records for sick animals. Records on individual study animals are kept in the primary animal room during the study and can be accessed by the Attending Veterinarian during the active study.

**4. Diagnostic Resources.** Describe available diagnostic methods used in the program including:

**a.** In-house diagnostic laboratory capabilities.

The CFSAN animal research program does not have in-house diagnostic capability.

**b.** Commercially provided diagnostic laboratory services.

**MOD-1**

Laboratory services are provided through IDEXX RADIL

**GCSL and Moffett Center**

Not Applicable

**c.** Necropsy facilities and histopathology capabilities.

**MOD-1**

Rooms 1512 and 1514 are fully-equipped necropsy rooms available for communal use by the veterinary staff and investigators. Histopathology is provided through a commercial source.

**GCSL**

Room 119 is used as the surgery/necropsy facility.

**Moffett Center**

Not Applicable

**d.** Radiology and other imaging capabilities.

The CFSAN animal research program does not have radiology or other imaging capabilities.

## 5. Drug Storage and Control

**a.** Describe the purchase and storage of controlled and non-controlled drugs.

**MOD-1**

The MOD-1 facility makes every effort not to use controlled drugs. If controlled drugs are needed, the Attending Veterinarian will order and control the substances. A safe is available for storage of controlled substances. Non-controlled drugs can be purchased either by the veterinarian or the Principal Investigator. Recommended storage arrangements for drugs, other than controlled substances, may include locked refrigerators/freezers and/or maintenance in a locked cabinet by the Principal Investigator.

**GCSL**

GCSL does not utilize controlled substances. All fish research drugs are used and stored in accordance with manufacturer specifications in laboratories, locked refrigerators, or locked freezers.

**Moffett Center**

Moffett Center does not utilize controlled substances.

**b.** Describe record keeping procedures for controlled substances.

**MOD-1**

The program makes every effort not to utilize controlled drugs. In the event a controlled drug was used, the procurement and disposal of controlled substance(s) would be carried out in compliance with DEA requirement by the licensed veterinarian. The licensed veterinarian would be responsible for administering the drugs and maintaining the records for any controlled substances used in the MOD-1 vivarium.

**GCSL and Moffett Center**

Not Applicable

## D. Surgery [*Guide*, pp. 115-123]

### 1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

**MOD-1**

There was only one approved surgical protocol. There are no current surgical protocols.

All surgical procedures were conducted in the dedicated surgical suite with surgical instrumentation also dedicated to the suite. A pre-operative room adjacent to the surgery suite was used to prepare the rats for surgery. The pre-operative room is equipped with gas anesthesia and appropriate scavenging and instrumentation required for preparing rats for surgery. A room dedicated to post-operative care was adjacent to the surgery suite. The room had circulating heating pads for maintaining body temperature during recovery, and has room temperature and humidity set to assist the rats in maintaining homeostasis during recovery.

The veterinary staff and the animal husbandry unit were notified in writing of planned surgical procedures. The research staff with assistance from the animal husbandry unit prepared the rats for surgery. A member of the veterinary staff routinely monitors anesthesia and provides oversight of the surgical procedures. Post-operative pain control was provided by the veterinary staff and post-operative observations are conducted by AHU, research study personnel, and veterinary staff.

**GCSL**

There are currently no approved surgical protocols.

**Moffett Center**

Not Applicable

### 2. Surgical Facilities [*Guide*, pp. 116-117, 144-145]

List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:

- the type of species (including rodents, fish, agricultural species, etc.)
- nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
- the amount of use [heavy (daily), moderate (weekly), or light]
- major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
- facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
- construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

*Note*: If preferred, the information requested in this section may be provided in Table.

**MOD-1**

There is a dedicated surgery suite on the first floor of the facility to accommodate aseptic surgical procedures. The suite consists of two operating rooms (1501 and 1503), and a surgeon scrub and gowning room (1602). The surgery suite is supported by one pre-operative room (1603) and two post-operative rooms (1607, 1609). The areas experience light to moderate use depending on the needs of the program.

**GCSL**

There are no approved surgical protocols at this time. If surgery protocols are submitted in the future, Room 119 is used for surgical procedures.

**Moffett**

Not Applicable

3. **Surgical Procedures** [*Guide*, pp. 117-118]

**a.** Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

The criteria that CFSAN follows for differentiation of major and minor surgical procedures are those found in the *Guide*. Specifically relative to procedures conducted within the Center's program, major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, craniotomy, joint replacement, and limb amputation).

Minor survival surgery does not expose a body cavity and causes little or no physical impairment (such as wound suturing, peripheral-vessel cannulation, biopsy, and most procedures routinely done on an "outpatient" basis in veterinary clinical practice). Animals are monitored through recovery from anesthesia and post-operatively in survival surgery.

**b.** How is non-survival surgery defined?

CFSAN does not have any non-survival surgery protocols. However, non-survival surgery would be defined as outlined in the *Guide.*

**4.** **Aseptic Technique** [*Guide*, pp. 118-119]

**a.** Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

**MOD-1**

The surgical site for all mammalian species is prepared by clipping the hair and washing and disinfecting the skin surface area. The instruments and supplies used during surgery are sterile. Protective clothing for surgeons or assistants that touch the animal or the sterile surgical area includes sterile gloves and gowns purchased as sterilized material from a commercial vendor, a hair cover, and surgical masks. Surgeons scrub prior to surgery and are aseptically gloved and gowned. Protective clothing for personnel that provide assistance but do not touch the animal or sterile surgical area includes a lab coat, hair cover, surgical mask, and gloves. If an instrument or clothing package appears to be damaged, it is not used. Aseptic techniques are employed during conduct of all surgical procedures including those conducted on rodents.

**GCSL**

Aseptic techniques in fish are difficult to maintain because of the constant flushing of the gills with a weak concentration of tricane methanesulfonate (MS-222) in water. Sterile instruments would be used in any surgeries involving fish.

**Moffett Center**

Not Applicable

**b.** Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

**MOD-1**

Instruments are thoroughly cleaned, packaged, and autoclaved. Sterilization indicators are used to monitor effectiveness. Sterile surgical attire (gowns, gloves, etc.) is purchased as such and disposed of after use. Sufficient instruments are available to provide an un- opened surgical pack for each rat during serial surgeries.

**GCSL**

Disposable materials required for surgical procedures that cannot be purchased as sterile are placed in small surgical packs and autoclaved. Every effort is made to purchase pre-sterilized disposable materials.

**Moffett Center**

Not Applicable

**c.** Describe methods for instrument re-sterilization between serial surgeries.

**MOD-1**

A separate set of sterilized instruments are used for each surgery. Each set of instruments is thoroughly cleaned, packaged, and autoclaved. Sterilization indicators are used to monitor effectiveness. Sterile surgical attire (gowns, gloves, etc.) is purchased as such and disposed of after use. Sufficient instruments are available to provide an un- opened surgical pack for each rat during serial surgeries.

**GCSL**

Disposable materials required for surgical procedures that cannot be purchased as sterile are placed in small surgical packs and autoclaved. Every effort is made to purchase pre-sterilized disposable materials.

**Moffett Center**

Not Applicable

**d.** Indicate how effectiveness of sterilization is monitored.

Sterilization indicators are used to monitor effectiveness.

**e.** Describe surgical support functions provided by the program to investigators.

All surgical protocols are fully supported by the program. The dedicated surgical suite and support rooms are maintained as part of the CFSAN animal research program. The equipment in the surgical suite is maintained by the facility. The animal research program provides funding to maintain and purchase surgical instruments and supplies including PPE required for the surgical protocol. The AHU provides technical support including but not limited to monitoring anesthesia, surgical assistance, pre-operative preparations and post-operative observations. The veterinary staff provides oversight of surgical procedures, manages post-operative pain, conducts post-operative observations and provides necessary veterinary care.

**GCSL**

There are no approved surgical protocols at this time.

**Moffett Center**

Not Applicable

**5. Intraoperative Monitoring** [*Guide*, p. 119]

Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

**MOD-1**

An individual animal anesthesia record is maintained for each rat undergoing a surgical procedure. Each record contains data on isoflurane concentration, heart rate (BPM), respiratory rate, capillary refill, mucus membrane color or percent oxygen saturation, and body temperature recorded at 15 min intervals. The CFSAN animal research program does not have any non-survival surgery protocols.

**GCSL**

Although there are no surgical protocols at this time, if such protocols are required in the future, postoperative monitoring will be conducted as described in the *Guide*. The research staff will be providing the postoperative care.

**Moffett Center**

Not Applicable

6. **Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

**MOD-1**

An individual post-surgical monitoring form is maintained for each animal undergoing a surgical procedure. Post-surgical care is provided by the animal husbandry and research staff with oversight from the veterinary staff. Animals are observed at least twice per day for typical behavior, and the incision site is examined for proper healing at least twice per day. Animals are provided Carprofen (Rimadyl) for pain under the direction of the veterinary staff. All observations and administration of pain medication are documented with date, time and signature of individual conducting observations and/or administering pain medications. All records are maintained in the post-operative recovery room and are available to the veterinary, AHU, and research staff as well as members of the IACUC. All records are transferred to the PI upon completion of the study.

**GCSL**

There are no surgical protocols, if such protocols are required in the future, postoperative care will be provided by the research staff.

**Moffitt Center**

Not Applicable

## E. Pain and Distress [*Guide*, pp. 120-121]

**1.** Describe how and by whom pain and distress are assessed.

**MOD-1, GCSL and Moffett Center**

Initially, the Principal Investigator assesses and categorizes the levels of pain and distress that the animals are anticipated to experience during the study in the protocol submission form. This judgment is based on literature searches, consultations with experts, and experience. The IACUC considers the pain category assignment during the protocol review and usually assigns that category which reflects the worst-case scenario when there is some uncertainty as to how the animals may respond. In some situations, there may be a request for reports to the committee as the study progresses.

**2.** Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

Training programs emphasizes on Basic general assessment of the individual animal species. This includes visual physical observation of the animals, hearing, palpation, smelling, their macro and micro environment. Trainee personnel will be shown video/audio presentations of normal/abnormal animals. Evaluation of the individual animal physical condition will include: Observation of body condition (fat, thin, emaciated, well flesh), body shape (swollen, enlarged), posture (hunched back), appearance of feather and fur (ruffled, shiny soft and smooth), facial expression, movement (wobbly, limping. or unable to move). Evaluation of the mucus membrane, eyes, ears, nose, skin, mouth, gums and teeth. Any abnormal findings must be reported to the attention of the attending veterinarian and PI immediately.

## F. Anesthesia and Analgesia [*Guide*, pp. 121-123]

**1.** List the agents used for each species.
*Note:* If preferred, this information may be provided in Table or additional Appendix.

**MOD-1**
Standard Operating Procedure AR-TP-005 Anesthesia and Analgesia Procedures describe the procedures for anesthesia and analgesia.
Mouse:
• Isoflurane
• Topical Lidocaine
Rat:
• Ketamine* (70 mg/kg)-Xylazine (8.6 mg/kg) given i.p.
• Isoflurane
Rabbit:
• Ketamine* (60 mg/kg)-Acepromazine (0.75 mg/kg) given i.m.
• Ketamine* (60 mg/kg)-Acepromazine (0.75 mg/kg)-Xylazine (5 mg/kg) given i.m.
• Butorphanol (0.4 mg/kg) given s.q.
• Isoflurane
• Topical Lidocaine
Pigs:
• Ketamine* (10.4 mg/kg)-Xylazine (2.1 mg/kg) given i.m., Acepromazine 1- 3 mg/kg given i.m., Isoflurane
*Ketamine is used at the discretion of the veterinary staff and is under the control of the Attending Veterinarian.

**GCSL**
Analgesia does not apply. The anesthetic agent used is tricaine methanesulfonate (MS-222) administered through water exposure (branchial absorption).

**Moffett Center**
None used

**2.** Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

**MOD-1**

The Principal Investigator consults with the veterinary staff about procedures to be conducted in a protocol. If drugs are to be used, the veterinarian provides guidance on selection and timing for use of drugs during the course of a study.

**GCSL and Moffett Center**

Not Applicable

**3.** Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

**MOD-1**
Anesthesia is monitored primarily by observing response to painful stimuli (e.g., toe pinch), respiratory amplitude and frequency, pupillary reflex, capillary refill, and mucous membrane coloration. A member of the veterinary staff, the principal investigator and/or study participant monitors administration of anesthetics and analgesics to study animals. The veterinarian provides guidance on selection of anesthetics and analgesics and provides general oversight of their use.

**GCSL**
As written in GCSL-AC-SOP No. 17 (rev. 1), tricaine methanesulfonate (MS-222) is dissolved in a 20-liter water bath at a concentration of 0.25 g/L. Fish are netted from the holding tank and placed in the anesthetic bath.
Within 5 minutes, fish should exhibit no response to handling and begin to lose their righting reflex. Procedures are performed rapidly (within 10 minutes) with the fish's gills bathed in water as much as possible during the procedure. For procedures requiring longer anesthetization (such as a dorsal aorta cannulation), fish are moved to a bath containing a lower concentration of MS-222 (e.g., 0.15 g/L). If opercular movement ceases, fish are returned to clean water and the gills are irrigated by gentle movement of the fish forward and backward to cause flow of water over gills or by use of a “turkey baster” which moves water gently over the gills to resuscitate the fish. These procedures are continued until opercular movement resumes. MS-222 is used according to manufacturer specifications. Fish condition is monitored by visual observation, personal experience with the agent, and general literature references.

**Moffett Center**
Not Applicable

**4.** Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

The CFSAN animal research program does not utilize neuromuscular blocking

agents.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

The isoflurane anesthesia vaporizer is sent every three years to an outside service company for calibration.

## G. Euthanasia [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   *Note:* If preferred, this information may be provided in Table or additional Appendix.

Methods of euthanasia for all species are reviewed by the IACUC and are in accord with the 2013 Report of the AVMA Panel on Euthanasia.
Euthanasia is always conducted in a room separate from the animal housing room(s).

**MOD-1**
Mice:
• CO2 Inhalation followed by thoracotomy, mice must be 14 days of age or older
• Cervical dislocation
• Decapitation; mice must be 14 days of age or younger

Rats:
• CO2 inhalation I followed by thoracotomy; rats must be 14 days of age or older
• Decapitation, rats must be 14 days of age or younger

Guinea Pigs:
• CO2 Inhalation followed by thoracotomy

Rabbits and Pigs:
• Acepromazine i.m. or Xylazine i.m., followed by general (isoflurane) anesthesia to effect followed by i.v. or intracardiac injection of potassium chloride (1-2 mmol/kg)

**GCSL**

Fish are anesthetized until opercular movement ceases. Each fish is then placed on an operating table, ventral side down, and a lateral incision is made with a knife midway between their skull and the anterior base of the dorsal fin. Using bone shears, a cut is made through the vertebral column.

**Moffett Center**
Cervical dislocation; mice must be 14 days of age or older.

**2.** Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

**MOD-1**

The quantity of carbon dioxide present in the respective tanks is monitored through the gas regulator to ensure a sufficient amount is present for appropriate euthanasia. Tanks of carbon dioxide are available in the facility at all times.

**GCSL and Moffett Center**

Not Applicable

**3.** Describe the methods used to confirm death of an animal.

**MOD-1**
The animal is observed for breathing, checked for absence of a heartbeat, and the thoracic cavity is opened to ensure death has occurred.
Esophageal stethoscope is used by the veterinary staff to confirm death in rabbits and pigs.

**GCSL**
A cut is made through the vertebral column.

**Moffett Center**
The animal is observed for breathing, checked for absence of a heartbeat, and the thoracic cavity is opened to ensure death has occurred.

**IV. Physical Plant** [*Guide*, pp. 133-155]

## A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

**MOD-1**

The animal housing and support areas of MOD-1 are located on the west side of the building. The majority of research animals are housed on the first and second floors and the majority of procedures are conducted on the first and second floors. Pigs are housed on the ground floor, and procedures are conducted on the ground or first floor. The ground floor also contains the animal support areas including the animal receiving bay, quarantine rooms, cage wash, bedding storage, laundry operation, storage areas, and administrative areas.

The facility is in the Office of Applied Research and Safety Assessment (OARSA) in the Center for Food Safety and Applied Nutrition. The facility manager and the Attending Veterinarian report directly to Dr. Mary Torrence, OARSA Director and CFSAN Institutional Official (IO). The Contract Officer Representative (COR) that has oversight of the animal husbandry contract is the facility manager

The IACUC Chairperson is in the Division of Toxicology (DOT) in OARSA. The Chairperson reports through DOT line management who report to the Director of OARSA. The Director of OARSA and the Institutional Official report through the CFSAN Deputy Director of Scientific Operations to Dr. Susan Mayne, the Director of CFSAN.

**GCSL**

The animal housing area is located on the north side of the GCSL building. Research animals are housed and procedures conducted only in Rooms 118 and 119.

The aquatic facility is in the Office of Food Safety (OFS) in CFSAN. The Animal Care Coordinator reports to the Chief of the Chemical Hazards Science Branch who also serves as the Principal Investigator for aquatic research. The Chief reports to the Director of the Division of Seafood Science and Technology who reports to the Director of the Office of Food Safety (OFS). The Director of OFS reports to the Deputy Director of Regulatory Affairs who reports to the CFSAN Center Director. The facility manager also reports to the Director of Seafood Science and Technology (DSST). The Animal Care Coordinator is a voting member of the IACUC and a member of the

aquatic research staff functions as the alternate.

**Moffett Center**

The animal housing area is located on the fourth floor of the Moffett Center. Research animals are housed in Room 409 within the select agent suite and all animal manipulations and procedures are conducted only in Room 411.

The mouse facility is in the Office of Food Safety (OFS) in CFSAN. The Animal Care Coordinator reports to the Chief of the Process Engineering Branch and the Animal Caretaker reports to the Chief of the Food Technology Branch. The Branch Chiefs report to the Director of the Division of Food Processing who reports to the Office of Food Safety. The Director of OFS reports to the Deputy Director of Regulatory Affairs who reports to the CFSAN Center Director. The Animal Caretaker is a voting member of the IACUC and a member of the animal research staff functions as the alternate.

## B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however, common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas

incorporating fewer or additional security features than the general features described.

7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

**MOD-1**

The animal area of MOD-1 is designed to function as a dual corridor (supply-side/return-side) facility and operates as a restricted-access clean conventional facility. There are two sets of elevators, one on the supply side and one on the return side. Doors separating the supply and return corridors are designed to prevent personnel from crossing from the return side to the supply side. In addition, the cores of the door locks have been removed to assure no one can access the rooms from the return side. Animals are not maintained outside of the animal facility; any procedures conducted in laboratories are terminal procedures that do not require housing in the laboratory.

The animal housing and support areas are physically separated from the research laboratories. Access into the animal facility on each floor is controlled by card readers at the entrances; authorized personnel have security badges recognized by the card readers. There are several procedure rooms within the animal facility, so investigators can perform technical procedures in these areas and return animals to holding rooms. If animal procedures must be conducted in laboratories, the animals can be transported to the laboratories through common use corridors in MOD-1. Only terminal procedures are conducted in laboratories outside of the animal facility.

For specialized housing, one quarantine cubicle room has been renovated to accommodate pigs and one room is used as the procedure room.

Although there are no active protocols, one room for utilizing radioactive materials is available within the vivarium.

The corridor walls in the animal area are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. The supply-side ceilings are double layered drywall with a Cocoon® finish, which is a sprayable vinyl coating, and are sealed at the walls and around light fixtures and air ducts. Ceilings in the return corridors are drop-in tiles that lock into place. The flooring is a sheet composition vinyl with integral coves and welded seams. Doors in the animal area are metal. Window ledges are made of heavy gauge, anodized aluminum. The corridors have stainless steel rails that run along both sides of the corridor, with stainless steel corner guards. The dimensions of the corridors are 8 ft. wide x 9 ft. 6 in. high. Doors are 3.5 ft. wide x 7 ft. high hollow metal doors with stainless steel bumper guards on the sides that enter and exit the animal room.
Doors in the 1800 and 21000 corridors have an additional 1 ft. wide panel that can

be opened to increase access to the room. Doors have a 100 sq. in. vision panel centered in the door with the midpoint of the panel located at a height of 5 ft. above the floor. Doors have automatic closures. The facility was designed to be easily sanitized. There are no exterior windows in animal rooms; however, the vision panels on the return-side of the 2600 (even) corridor face exterior windows allowing natural light into the rooms. Natural light transmission can be minimized by thick magnetic window covers over the vision panels in the doors.

The HVAC system is adequate to reliably meet the temperature, humidity, and ventilation (pressure gradient and air exchange rate) requirements of the *Guide* for the species housed in the facility. Heating and air conditioning are regulated by a dedicated Johnson Controls Tritium system. All air entering the facility is 100% fresh and MERV- filtered. Trim humidifiers maintain the relative humidity in each animal room within a range appropriate for the species housed in that area. Contract facilities maintenance personnel monitor environmental parameters of individual rooms on a continuous basis (i.e., 24 hr/day without interruption). For energy conservation, environmental conditions are not maintained in unoccupied animal rooms.
All system equipment components and animal housing rooms are monitored 24/7/365 by the onsite O&M engineer. The system equipment components are also physically inspected and logged three times a day or once per shift by the onsite engineers. Any faults, errors, or alarms are alerted on the facility Building Automation System (BAS). Any faults, errors, or alarms pertaining to the equipment systems are acted upon and resolved with expedience. Any faults, errors, or alarms that involve an active animal room are promptly investigated and repaired. If the situation is not capable of an immediate resolution, a request is made to transfer the animals to a functional back-up room until the repairs can be completed and fully tested.

The Muirkirk Road Complex (MRC) is comprised of three separate components, MOD-1, MOD-2, and the Beltsville Research Facility (BRF). MOD-1 houses the CFSAN vivarium, research labs, and offices. MOD-2 houses the Center for Veterinary Medicine (CVM) research laboratories, offices, and animal facilities. BRF is used by CVM. MRC is enclosed within a chain link security fence with barbed wire at the top. The entrance to the facility is manned by security staff 24/7/365 days. A valid smart card is required for employees to access the complex through the control point at the manned entrance to the complex.
There are two entrances to the MOD-1 building, a front entrance leading to the atrium and a back entrance at the loading dock. Employees must show a valid FDA ID card to the security guards upon entering the building. Personnel entering or exiting from the building outside of the 6:00 am to 6:00 pm core hours, or entering the building on weekends and holidays must sign the log book maintained at the security desk.

Visitors must produce a valid driver's license (or other acceptable government issued identification such as a passport) for entrance onto the facility grounds. Visitors register with security to obtain a temporary identification card that must be

displayed at all times. Visitors and their belongings (brief cases, purses, lunch containers etc.) must proceed through security screening prior to gaining access to the MOD-1 facility. Visitors are escorted by a MOD-1 employee at all times while within the MOD-1 facility including the animal facility.

Entrance to the animal facility is controlled by smart card security card readers. Each room has a unique key lock, and a key specific to the designated study room is provided to the investigator utilizing the space. Keys are collected at the end of a study. Each floor has a submaster key specific to the rooms on that floor. The veterinary staff, animal husbandry contract manager, IACUC chairperson, and the CFSAN Research Facility Manager are the only personnel who have master keys for the vivarium.

Cleaning agents and disinfectants are stored in janitorial closets present on each floor of the animal facility. Bulk storage is also available on the ground floor of the animal facility in the cage wash area. Storage cabinets such as flammable and acid storage cabinets are also available as needed. Pesticides are not stored in the animal facility. Diesel fuel is stored in outside fuel storage tanks.

## C. Satellite Animal Housing Facilities

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17)**, "Satellite Animal Housing Areas."

**1.** Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

**GCSL**

The animal area of the GCSL is a conventional aquaculture facility.
Animals are not maintained outside of the aquaculture facility.
The floors of Rooms 118 and 119 (animal holding, and necropsy/surgery) are concrete and surfaced with epoxy flooring containing anti-skid texturing. Fish room walls are cinder-block coated with block filler and three coats of epoxy paint. Fish room ceilings are drop-ceilings in design and are composed of Armstrong Ceramic-Guard™ panels. Interior access doors are double-swing, 3 ft. wide and 7 ft. high. They are hollow steel doors with safety-wire vision panels and aluminum kick-plates. Exterior access doors are of aluminum construction of the same design and dimensions but without safety wire at the windows.

There are no exterior windows; however, the exterior doors have panels allowing natural light into the room.

**Moffett Center**

The area of the Moffett Center is a conventional small animal facility; animals are not maintained outside of the mouse facility.
The floors of Rooms 409 and 411 are concrete and surfaced with epoxy flooring containing anti-skid texturing. Walls in the animal area are cement masonry units (cement masonry block) coated with block filler and two coats of epoxy paint. Ceilings in the animal rooms are double-layered drywall and are sealed at the walls and around light fixtures and air ducts. Interior access doors are single-swing, 3 ft. wide and 7 ft. high. They are hollow steel doors with safety-wire vision panels and aluminum kick-plates. Exterior access doors are of stainless steel construction of the same design and dimensions. There are no exterior windows; however, the exterior doors have integrated safety-wire vision panels.

**2.** Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

Semi-annual facilities inspections (including the satellite facilities) are conducted every 6 months. A member of the IACUC (usually the IACUC Chairperson) will physically inspect the facilities once every three years and more often when USDA regulated animals are being utilized for approved (b) (4) studies. Before animal work can be done on an approved animal study protocol, the satellite facility will be inspected by the IACUC Chairperson. The Attending Veterinarian has access to all animal facilities in the CFSAN animal research program, including all satellite facilities.

## D. Emergency Power and Life Support Systems

*Note:* Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

**1. Power** [*Guide*, p. 141]
For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

**MOD-1**
There are five emergency generators which automatically sustain the electrical load in case of power outage. Two 350 kW generators located at the front of the building operate on diesel fuel from a 1,000 gallon above-ground tank. Both can operate for about 72 hours without refueling and supply power for emergency lighting and the emergency electrical outlets. At the rear of the building are three generators, two 635 kW and one 1,000 kW, that supply power for major equipment items (e.g., boilers, chillers, air handlers, elevators). These latter three are diesel fueled from two 30,000 gallon below-ground tanks. There is sufficient capacity under normal load to maintain satisfactory air flow, heating, cooling, and lighting to animal rooms for approximately 3 days. The operations and maintenance contractor tests the emergency generators under load conditions monthly.

**GCSL**
The GCSL facility has one emergency and one auxiliary generator. The 300 kW emergency generator is an automatic-on unit when power failure occurs and automatic-off when power is restored. It services all emergency circuits in the facility, including the fish holding areas. The 200 kW generator is a manual start-manual transfer system. This generator has sufficient capacity to maintain the entire facility. Both generators are diesel fueled and facility storage capacity is 10,000 gallons, sufficient for approximately 30 days of operation.

**Moffett Center**
The animal facility has one emergency and one auxiliary generator. The 50 kW emergency generator is an automatic-on unit when power failure occurs and automatic-off when power is restored. It services all emergency circuits in the select agent suite, including the animal holding areas.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

**MOD-1**

Since the time animals have been housed at MOD-1, there have been numerous power failures, brownouts, and power interruptions. In every case, the emergency generators were able to maintain acceptable environmental conditions in the animal rooms. There have been no animal deaths resulting from power loss.

**GCSL**

Power failures occur approximately 7-8 times per year and average approximately 5 hours duration. Environmental conditions are maintained within prescribed parameters by emergency power provisions. There have been no animal deaths resulting from power loss.

**Moffett Center**

None to report at this time.

No animal loss or health issues have occurred due to power, HVAC, or life support failures.

## E. Other Facilities [*Guide*, pp. 144, 150]

### 1. Other Animal Use Facilities [*Guide*, pp. 146-150]

Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

Not Applicable

### 2. Other Animal Program Support Facilities

Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

**MOD-1 and Moffett Center**

Not Applicable

**GCSL**

Room 119 is used to prepare the squid and shrimp for feeding red snapper. The squid is cut up and distributed into Ziploc bags. The shrimp is kept whole and distributed into Ziploc bags. The bags are kept in the -20° C freezer in Room 120.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution´s animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at: accredit@aaalac.org

# Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

| Abbreviation/Acronym | Definition |
|---|---|
| FDA | U.S. Food and Drug Administration |
| CFSAN | Center for Food Safety and Applied Nutrition |
| OARSA | Office of Applied Research and Safety Assessment |
| MOD-1 | Module 1 |
| GCSL | The Gulf Coast Seafood Laboratory |
| MCAF | Moffett Center Animal Facility |
| COR | Contracting Officer's Representative |
| DOT | Division of Toxicology |
| DRTIB | Developmental/Reproductive Toxicology and Immunotoxicology Branch |
| RO | Responsible Official |
| FOH | Federal Occupational Health |
| AEP | Animal Exposure Program |
| OHSE | Occupational Health Surveillance Examination Program |
| EMR | Electronic Medical Record |
| | |
| | |

# Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

| Animal Housing and Support Sites | | | | | | |
|---|---|---|---|---|---|---|
| **Location (building, site, farm name, etc.[a])** | **Distance from main facility[b]** | **Approx. ft², m², or acreage for animal housing** | **Approx. ft², m², or acreage for support or procedures** | **Species housed** | **Approx. Daily Animal Census by species** | **Person in charge of site** |
| MOD-1 | ● | 12,224 | 16,155 | mouse | ● | M. Torrence |
| MOD-1 | ● | 12,244 | 16,155 | rat | ● | M. Torrence |
| MOD-1 | ● | 12,244 | 16,155 | rabbits | ● | M. Torrence |
| MOD-1 | ● | 12,244 | 16,155 | guinea pigs | ● | M. Torrence |
| MOD-1 | ● | 12,244 | 16,155 | pig | ● | M. Torrence |
| MOD-1 | ● | 12,244 | 16,155 | poultry | ● | M. Torrence |
| MOD-1 | ● | 12,224 | 16,155 | mouse | ● | M. Torrence |
| **Satellite Housing Facilities Total** (Expand in Table 17) | | | | | | |

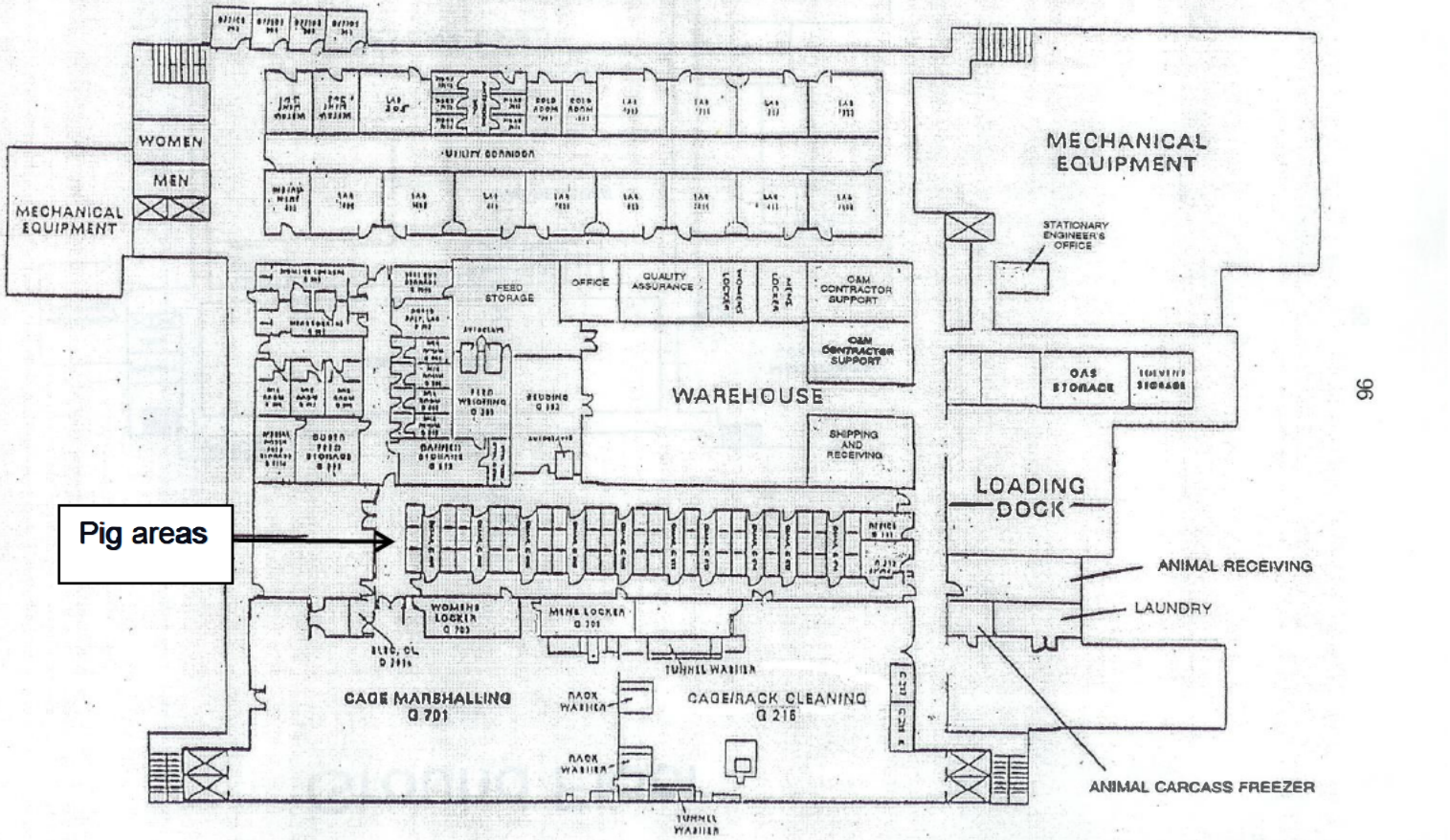
| | | |
|---|---|---|
| **Totals:** | 12,224 | 16,155 |
| **Total animal housing and support space:** | **(please specify ft² or m²)** | |

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

# Appendix 3: Floor Drawing(s)

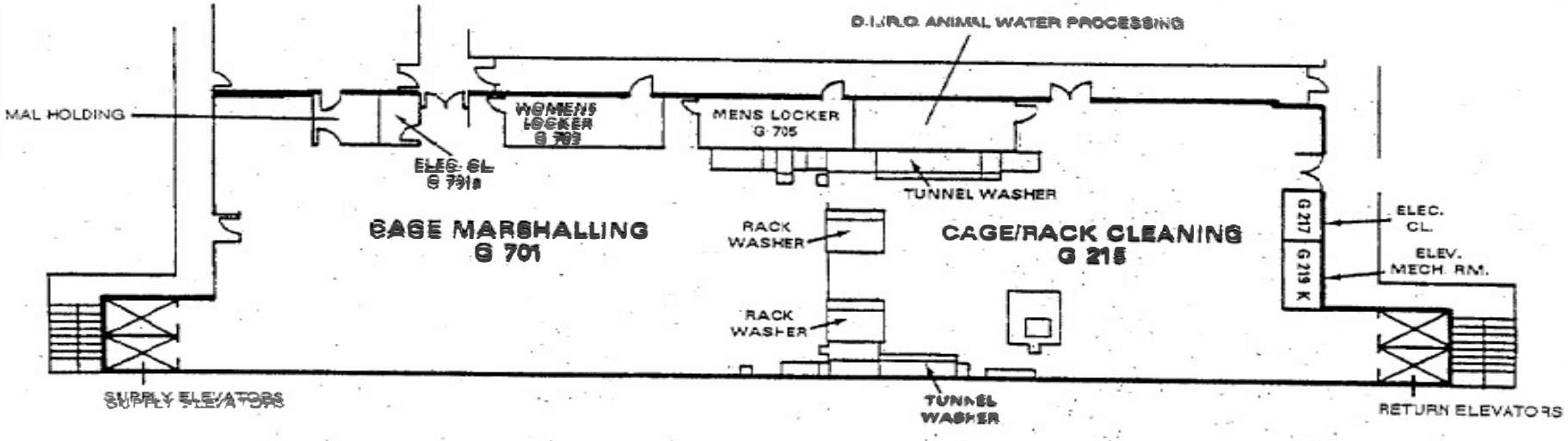
Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5” x 11” or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

# MOD I
# GROUND FLOOR

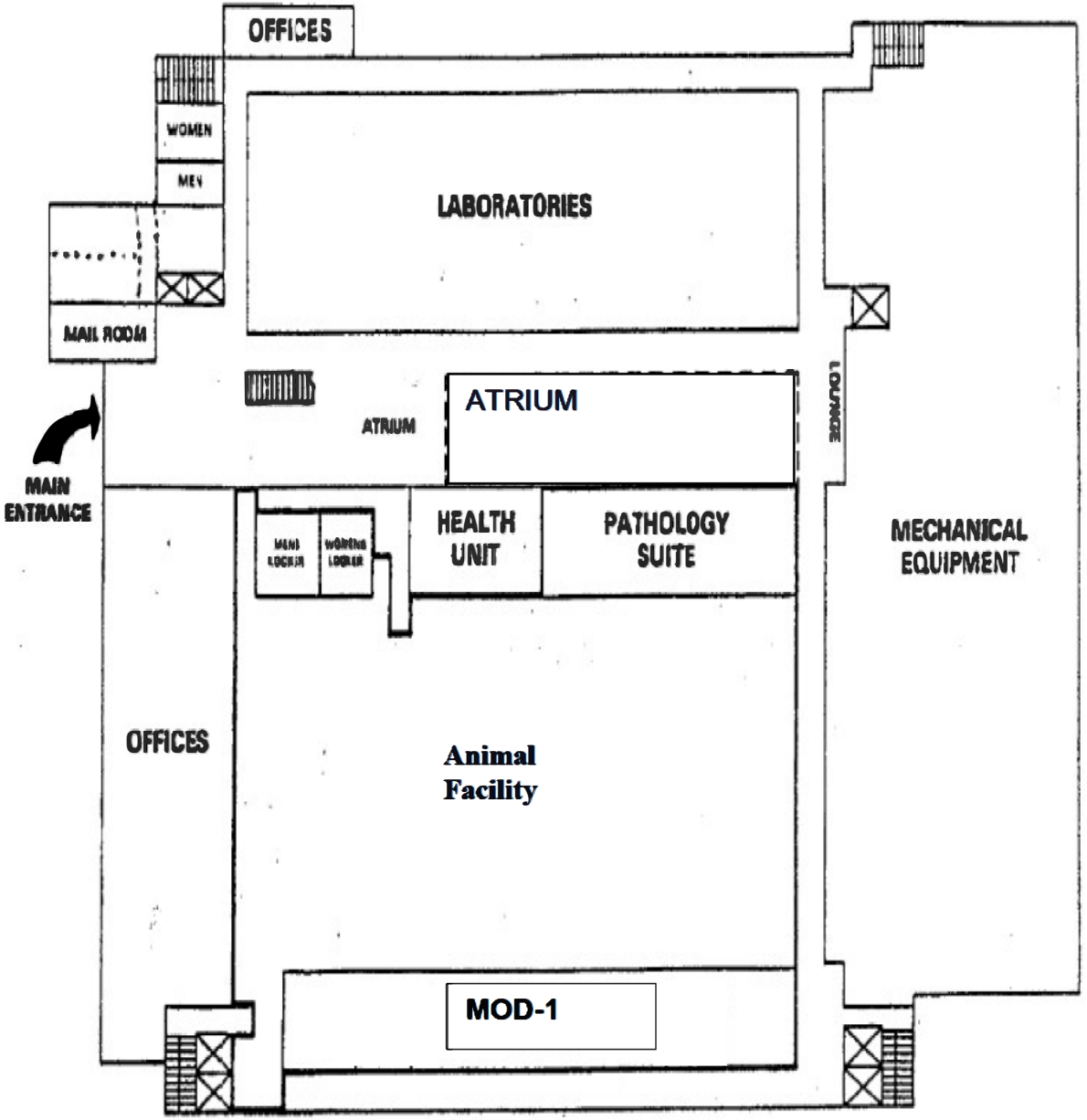



96

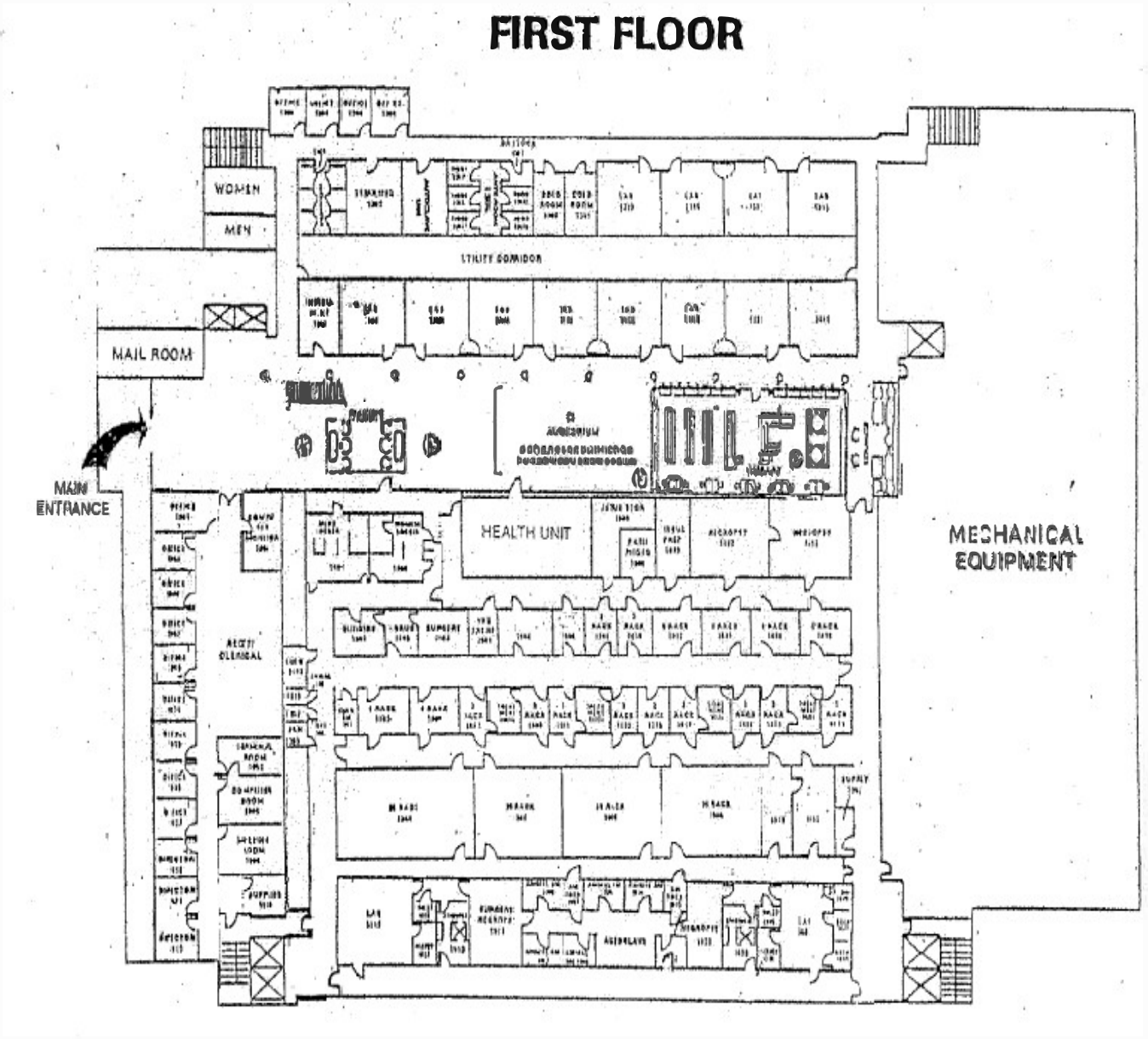
# MOD I
# GROUND FLOOR
# CAGE MARSHALLING AND
# CAGE & RACK WASHING



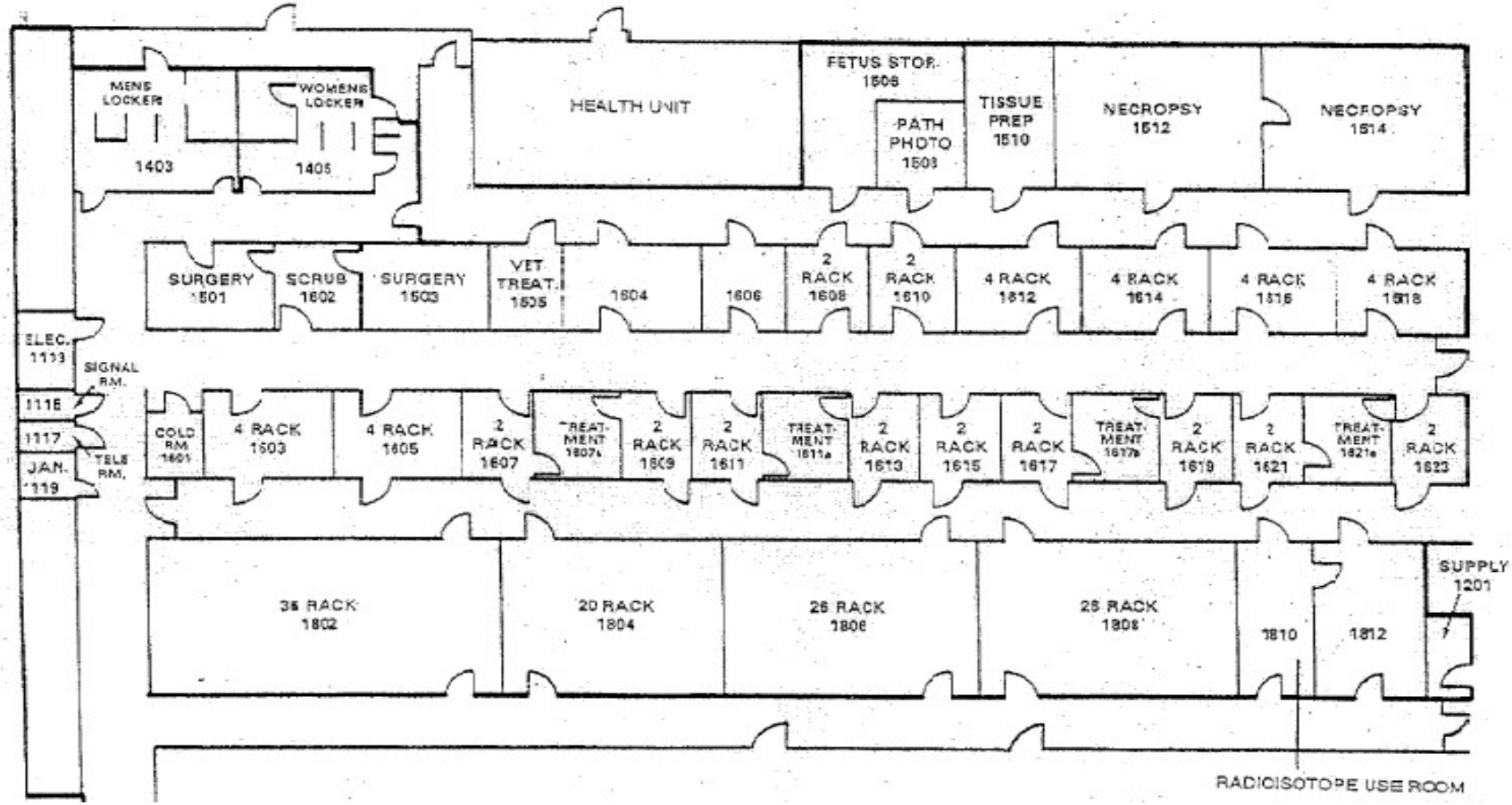
# FIRST FLOOR


OFFICES
WOMEN
MEN
LABORATORIES
MAIL ROOM
ATRIUM
ATRIUM
LOUNGE
MAIN ENTRANCE
HEALTH UNIT
PATHOLOGY SUITE
MECHANICAL EQUIPMENT
OFFICES
Animal Facility
MOD-1

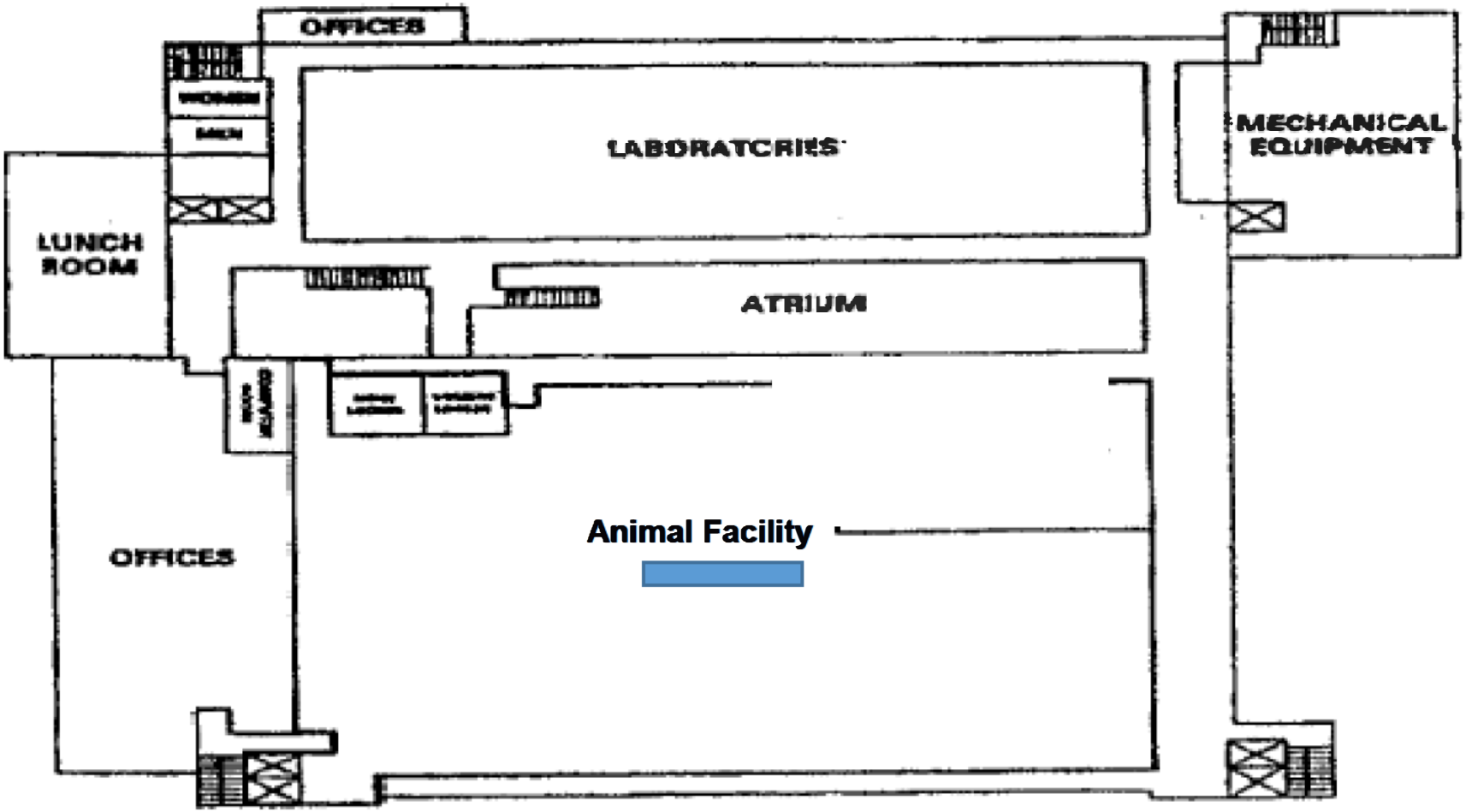
# FIRST FLOOR


WOMEN
MEN
UTILITY CORRIDOR
MAIL ROOM
MAIN ENTRANCE
HEALTH UNIT
MECHANICAL EQUIPMENT

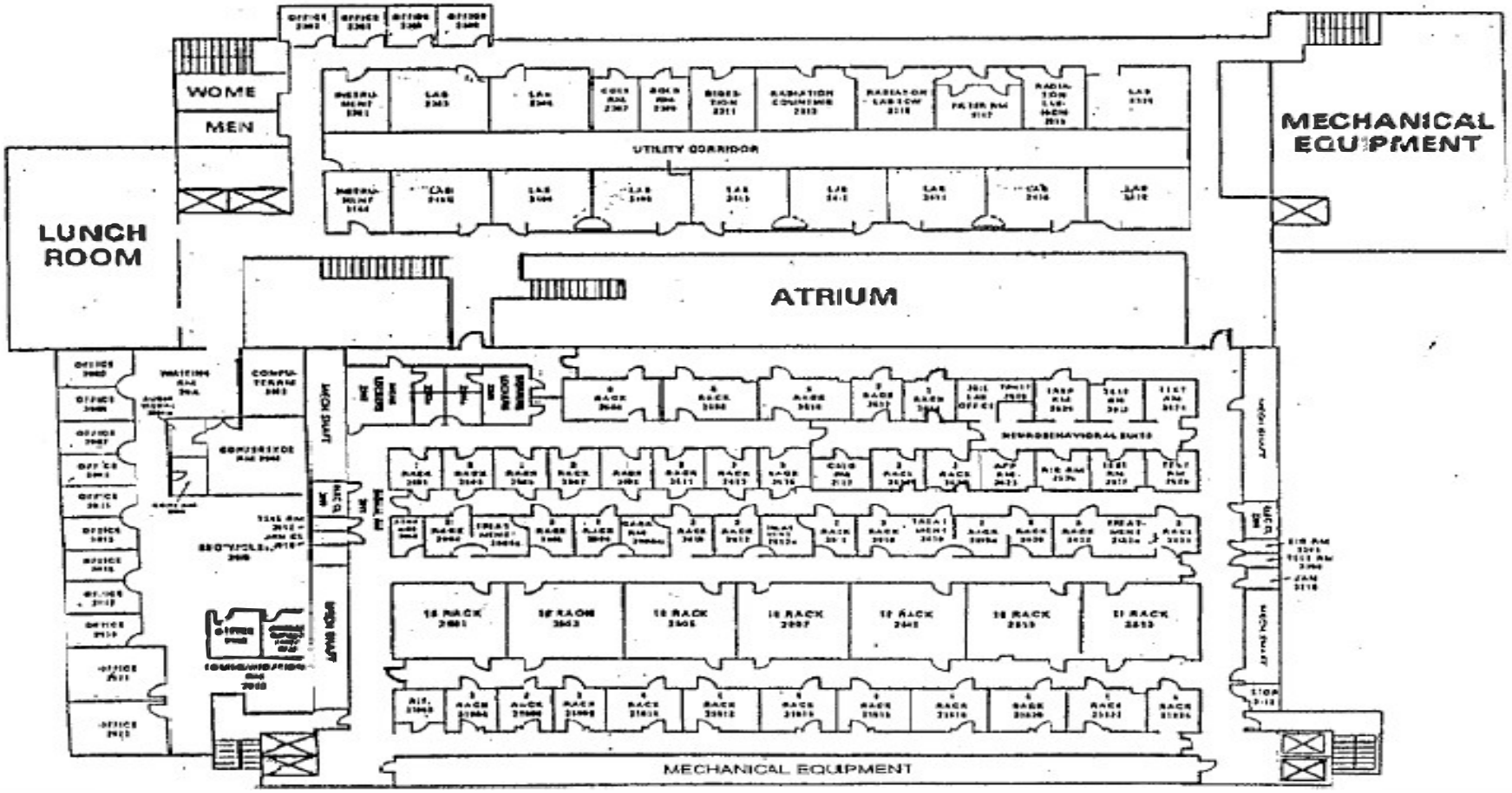
# MOD I
# FIRST FLOOR
# & PATHOLOGY SUITE



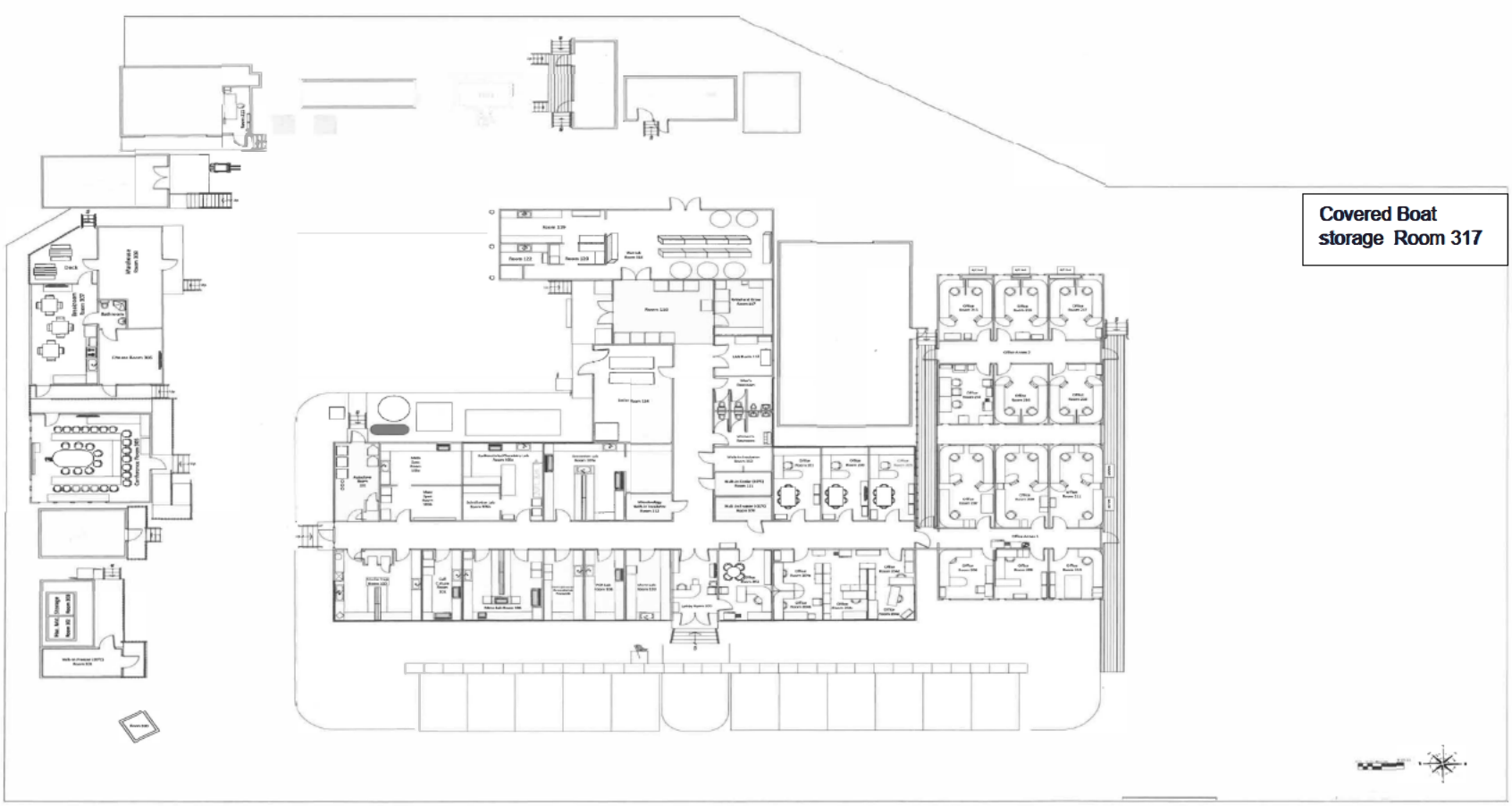
# Second Floor
## MOD-1



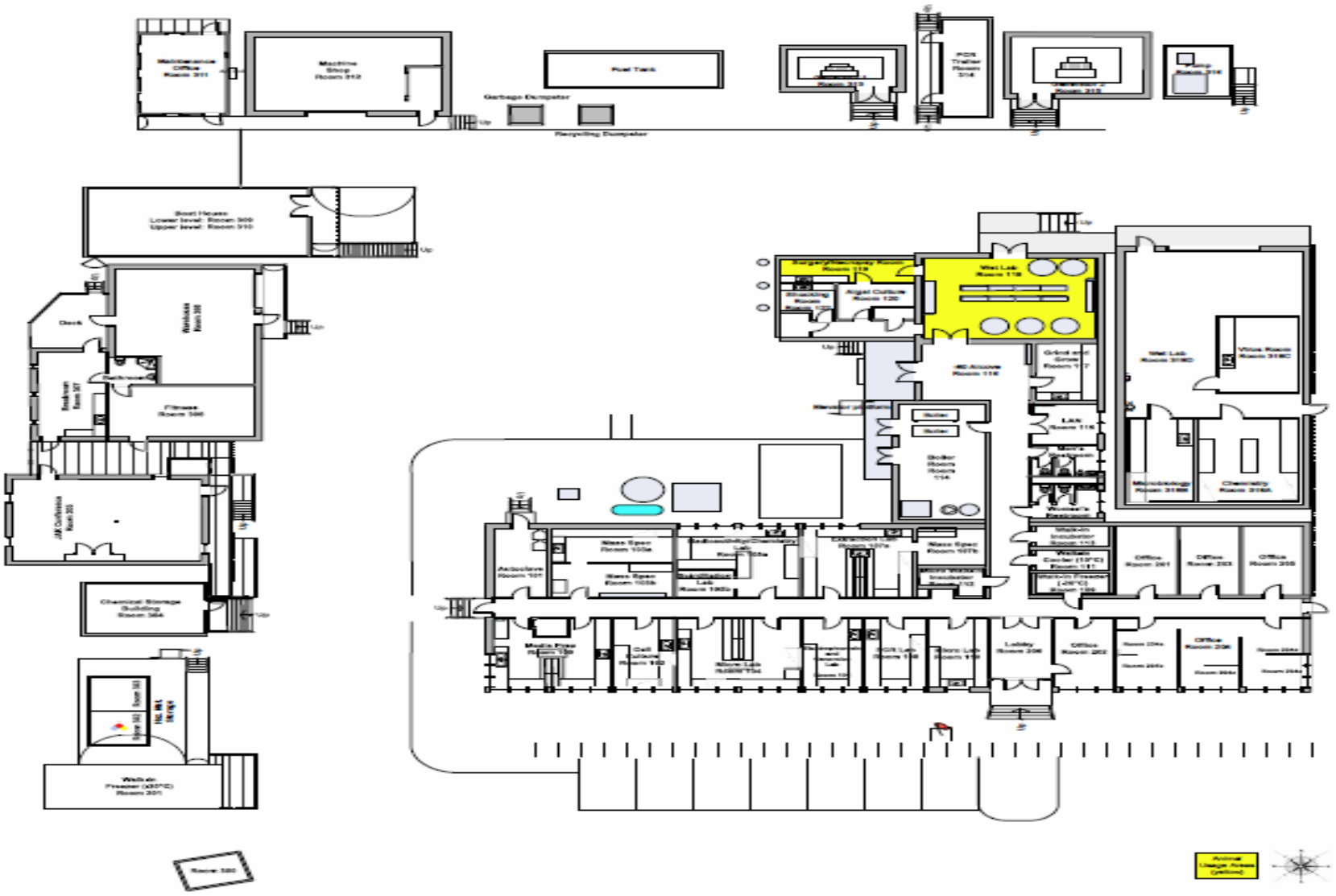
# MOD I
# SECOND FLOOR



# GCSL Facility



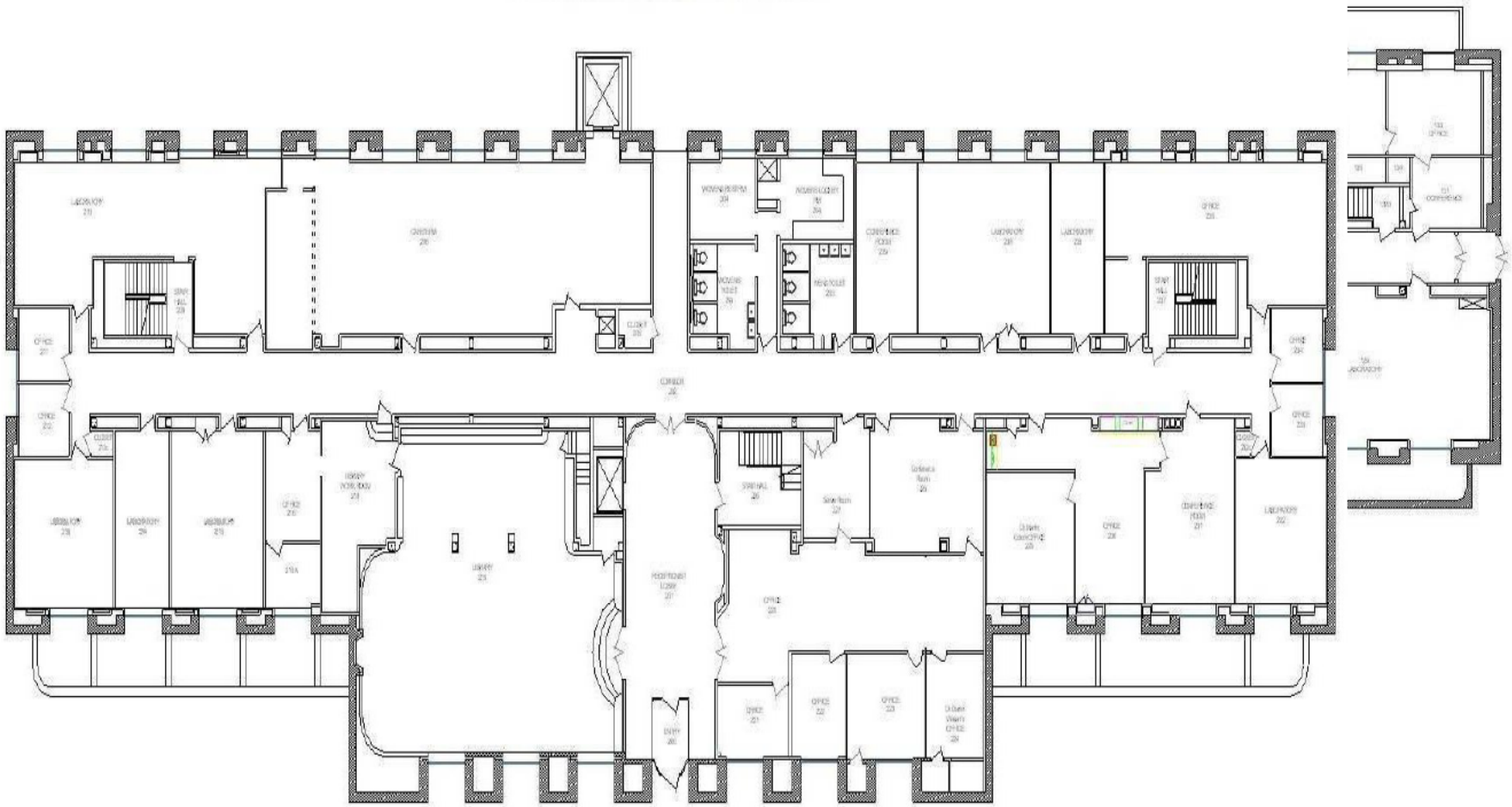
Gulf Coast Seafood Laboratory



# Moffett Center

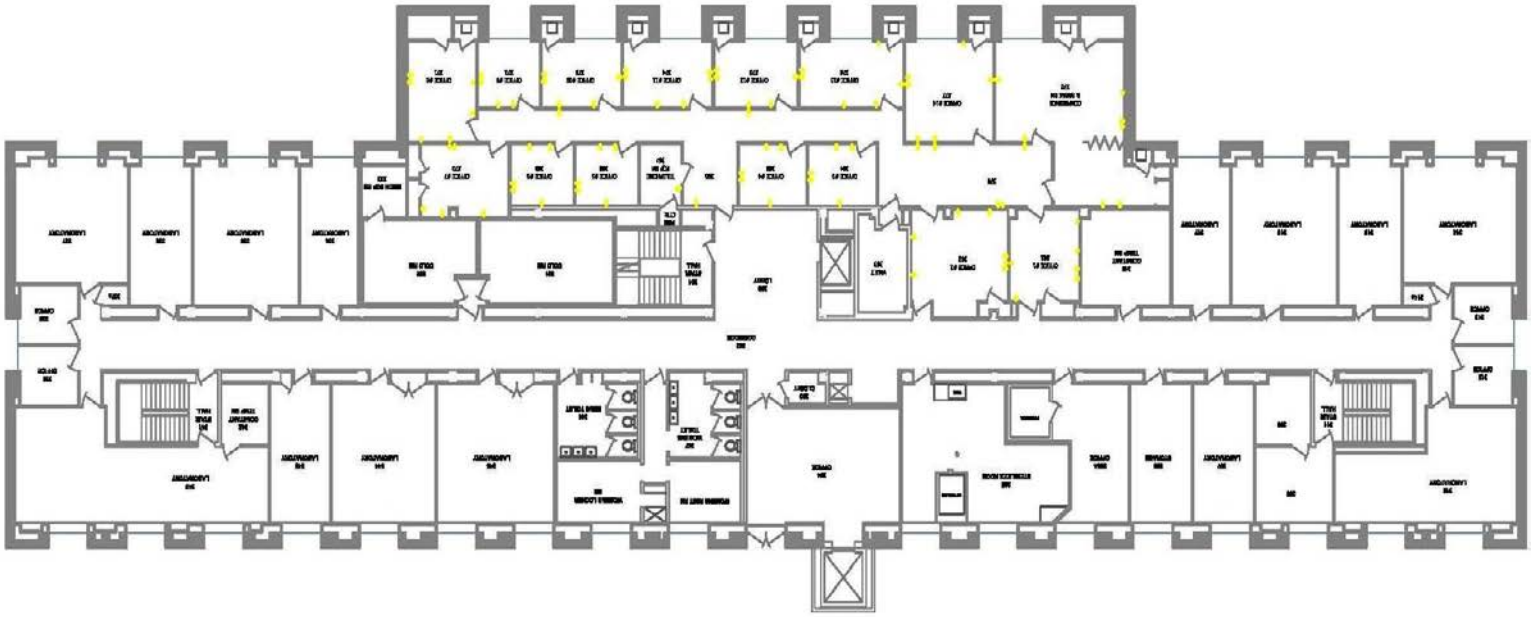
# Moffett Center

## SECOND FLOOR - BLDG 90



# Moffett Center

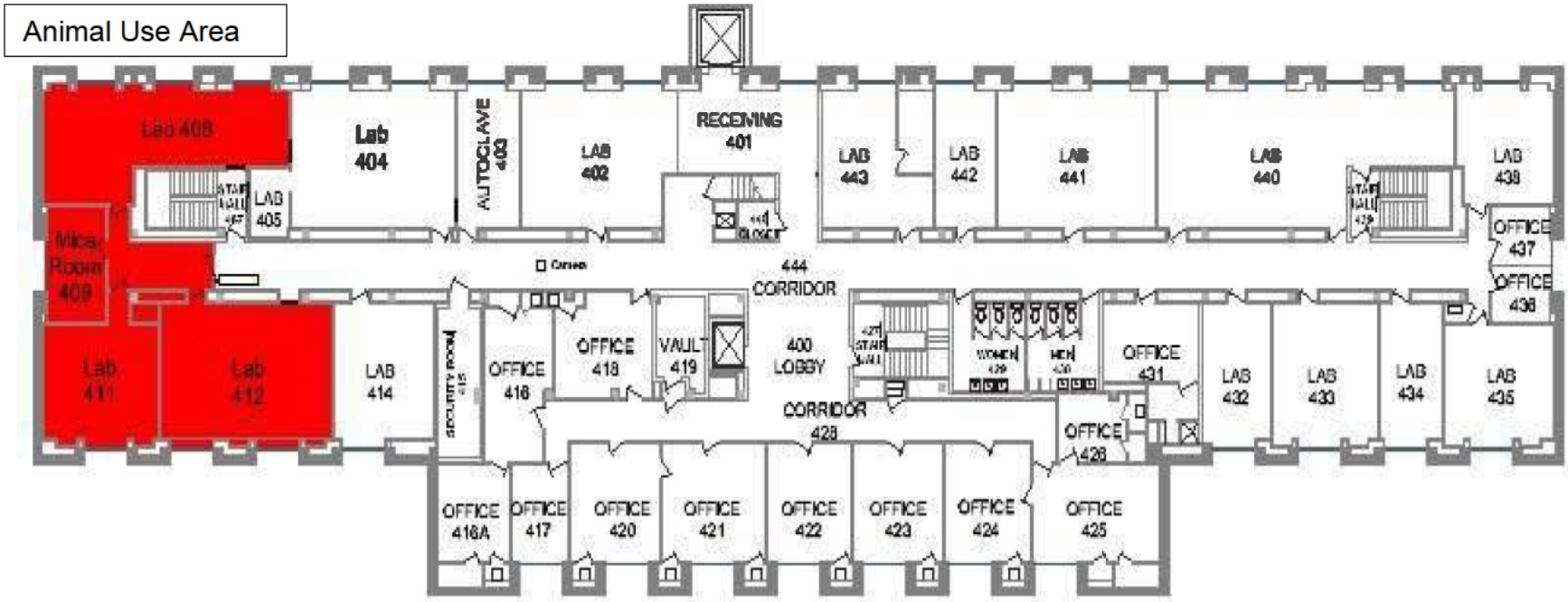
# Third Floor Office Space



# Moffett Center

# Fourth Floor

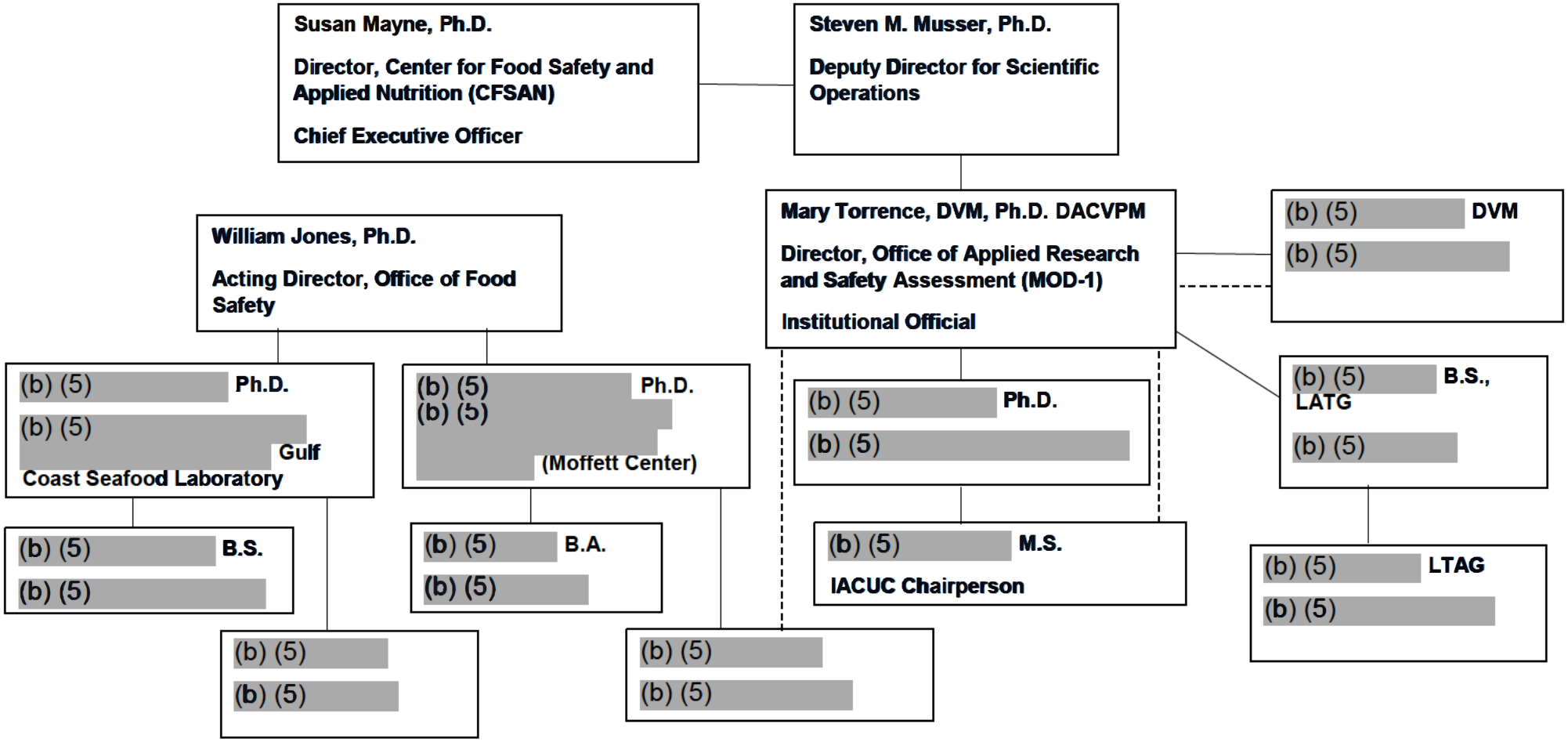
Animal Use Area



# Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

## Center for Food Safety and Applied Nutrition Animal Program Lines of Authority



# Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| Research animal health monitoring and surveillance program for MOD-1 animals | 10-004 | (b) (5) | mouse and rat | Animals approved as needed for sentinels | D | | | | | X | |
| To compare laying hen reproductive tissue invasion and colonization with *Salmonella enterica* serovars Enteritidis, Heidelberg, Typhimurium and Hadar using *in vivo* and *ex vivo* models | 11-003 | (b) (5) | chicken | 300 | C | | | | | X | |
| *Listeria monocytogenes* infection of mice for investigating the role of | 11-006 | (b) (5) | mouse | 420 | E | | | | | X | |

# Appendix 5: Animal Usage

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| interleukin-17 receptor (IL-17R) signaling in host defense and | | | | | | | | | | | |
| Assessing the potential of select dietary supplements to adversely affect cardiovascular function in the rat | 14-004 | (b) (5) | rat | 336 | E | X | | | | | |
| Anesthesia and surgery training protocol for telemetry | 14-001 | (b) (5) | guinea pig and rat | 20 | E | X | | | | | |
| Inoculation of mice for the production of immune serum (IgM+IgG) and lymphocytes | 053-E | (b) (5) | mouse | 120 | E | | | | | X | |
| Production of polyclonal antibodies in rabbits | 059-E | (b) (5) | rabbit | 60 | D | | | | | X | |
| Acute oral toxicity of diglycolic acid (DGA) in rats: up and down procedure and pilot | 14-002 | (b) (5) | mouse | 100 | E | | | | | X | |

# Appendix 5: Animal Usage

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| 28- day repeated dose toxicity study | | | | | | | | | | | |
| Probiotic supplementation and attenuation of inflammatory immune responses elicited by food allergens using a mouse model | 10-001 | (b) (5) | mouse | 462 pups 60 dams | E | | | | | X | |
| Assessing the potential of select dietary supplements to adversely affect cardiovascular function | 14-003 | (b) (5) | guinea pig | 336 | E | X | | | | | |
| Maintenance of the gene knockout mice (CD73- KO & IL17R-KO) breeding colony | 10-003 | (b) (5) | mouse | Breeding colony | B | | | | | | |
| Maintenance of the toll-like receptor 11 gene knockout | 15-002 | (b) (5) | mouse | Breeding colony | B | | | | | | |

# Appendix 5: Animal Usage

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| mice (TLR11-KO) breeding colony | | | | | | | | | | | |
| Development of a novel *in vivo* model to confirm virulence of non-O157:H7 toxin producing *E. coli* (STEC) food isolates | 15-001 | (b) (5) | mouse | 930 | E | | | | | X | |
| Percutaneous absorption of dendrimer nanoparticles in pig skin | 11-005 | (b) (5) | pig | 24 | C | | | | | | |
| Confirmation of *Clostridium botulinum* DIG ELISA sensitivity in food commodities | 13-002 | (b) (5) | mouse | 4264 | E | | | | | X | |
| Virulence Assessment of Foodborne Microbial Pathogens | 15-004 | (b) (5) | mouse | 72 dams ~ 576 pups | E | | | | | X | |
| CFSAN Animal Research Training Protocol | 561 | (b) (5) | Mouse<br>Rat<br>Rabbits<br>Chickens | 300<br>150<br>30<br>30 | C | | | | | | |

# Appendix 5: Animal Usage

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| | | | pigs | 15 | | | | | | | |
| CFSAN Animal Research Holding Protocol | 562 | (b) (5) | Identified by amendment | Animals approved as needed | B | | | | | | |
| General Skin and Buccal Absorption Protocol | 566-10-17 | (b) (5) | Pigs<br>Hairless Guinea pigs<br>Buccal cheeks | 45<br>90<br><br>180 | C | | | | | | |
| Detection of *Clostridium botulinum* Toxin from Regulatory Sample | 567-6-18 | (b) (5) | mouse | 2700 | E | | | | | | |
| | | | | | | | | | | | |

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)

# Appendix 5: Animal Usage

(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)
(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

| |
|---|
| |

In the Table below, provide an approximate annual usage for all species:

| Animal Type or Species | Approximate Annual Use |
|---|---|
| Mice | 593 |
| Rats | 33 |
| Rabbits | 17 |

| Animal Type or Species | Approximate Annual Use |
|---|---|
| Chickens | 78 |
| | |
| | |

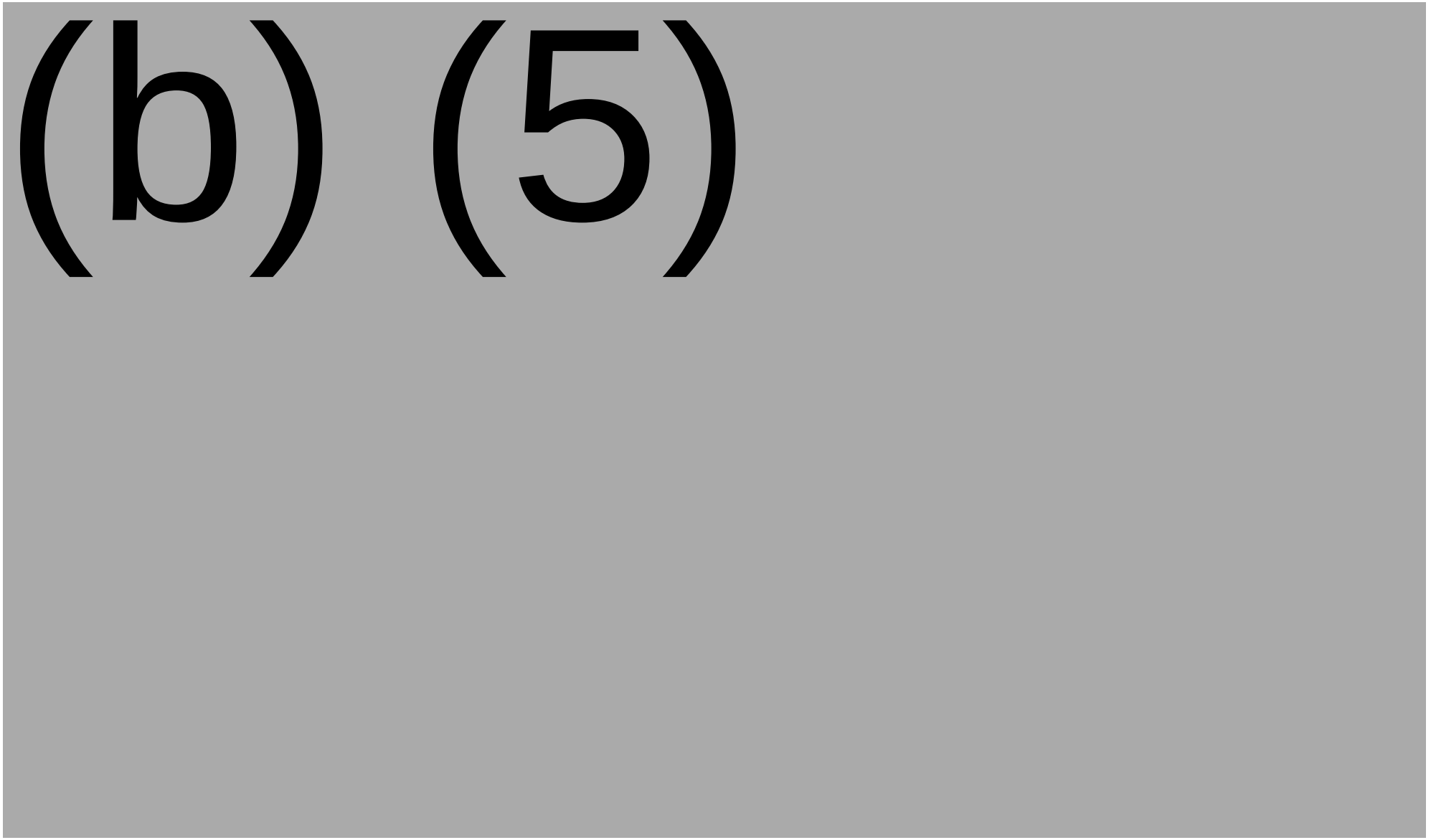
[Create additional rows by pressing TAB in the bottom-right box.]

# Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

**SEE ATTACHMENTS**

## Appendix 7: IACUC/OB Membership Roster



# Appendix 8: IACUC/OB Minutes

Please provide the latest two Minutes of the IACUC/OB meetings.

SEE ATTACHMENT

# Appendix 9: Blank IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**PUBLIC HEALTH SERVICE**

**FOOD AND DRUG ADMINISTRATION**

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**

**ANIMAL STUDY PROTOCOL**

**Leave Blank**
BFQ #:

USDA Pain Code:

Approval Date:

**PLEASE TYPE. Form ASP01 must be completed for approval of each animal study conducted in CFSAN. Fill out the form completely; indicate with *N/A* any sections that are not applicable.**

**A. ADMINISTRATIVE DATA**

Study Classification: ☐Initial Submission ☐Renewal BFQ#

CARTS Number: (CFSAN Only)

GLP Study: ☐ Yes ☐ No

Select Agents: ☐ No ☐ Yes If Yes Indicate Agent(s): ☐ Viable organism ☐ Toxin

| | |
|---|---|
| Protocol Title: | |
| | |
| Principal Investigator or Study Director: | |
| | |
| Center/Office/Division | |
| | |

| |
|---|
| List the names of all individuals authorized to conduct procedures involving animals under this protocol *(if individuals are from outside of the Center please provide their department, telephone, fax, and email)*: |
| A training and experience form (Appendix 1) is required for each individual conducting procedures involving animals. For any training needs complete the Training Requests form (Appendix 2). |
| |

| | | | | | |
|---|---|---|---|---|---|
| **Telephone:** | | Fax: | | **Email:** | |

## B. STUDY OBJECTIVES

| Briefly explain in language understandable to a layperson the aim of the study and why the study is important to human or animal health, the advancement of knowledge, or the good of society. Explain the relationship of this study to the mission of the Center. |
| --- |
| |

## C. ANIMAL REQUIREMENTS

| | | | |
|---|---|---|---|
| Genus: | *[e.g., Mus]* | Species: | *[e.g., musculus]* |
| | | | |
| Strain, subspecies, or breed: | *[e.g., C57BL]* | Common name: | *[e.g., black laboratory mouse]* |
| | | | |
| Approximate age, weight or size: | | | |
| | | | |
| Maximum age, weight or size for use on the protocol: | | | |
| | | | |
| Sex: | | | |
| | | | |
| Bacteriological status: | *[e.g., germfree (axenic), defined flora (gnotobiotic), specific pathogen free, conventional]* | | |
| | | | |
| Source(s): | *[e.g., name of vendor or breeder, bred in-house]* | | |
| | | | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | |
| Location(s) where study will be conducted: | | ☐ MOD-1 | ☐ GCSL | ☐ Moffett Center | |
| | | | | | |
| Number of Animals to be Used: | | | | | |
| Year 1: | | Year 2: | | Year 3: | |
| Total: | | | | | |

**D. STUDY INFORMATION**

| *In vivo* Study – Test Article | |
|---|---|
| a. Name of Article: | b. CAS No. |
| | c. LOT No. |
| d. Characteristics (strength, purity etc.): | e. Stability |
| | f. Source |

| *In vivo* Study – Control Article | |
|---|---|
| a. Name of Article: | b. CAS No. |
| | c. LOT No. |
| d. Characteristics (strength, purity etc.): | e. Stability |

| | |
|---|---|
| | f. Source |

| *In vivo* – Test and Control Articles | | | |
|---|---|---|---|
| a. Material Used to Solubilize or Suspend Articles: | b. Preparation Recipe | | |
| | Dosage Level | Grams Test Article | Grams Control Article |
| c. Route of Administration and Reason for Choice: | | | |
| d. Specification for Acceptable Levels of Interfering Substances: | | | |

| *In vivo* Study – Test System *(insert additional rows placing the curser in the last column of the table, holding down the Alt key and pressing the A Key* | | | | | |
|---|---|---|---|---|---|
| a. Species | | b. Strain | | c. Substrain | |
| Name of Article | CAS No. | Lot No. | Purity | Source | Dosage |
| | | | | | |

| Animals: |
|---|

| | Males | | Females | |
|---|---|---|---|---|
| Number of Animals | | | | |
| Age of Animals | | | | |
| Initial Body Weight Range | | | | |
| Identification Numbers: *(Insert additional rows by placing the curser in the last column of the table, holding down the Alt Key and pressing the B Key)* | | | | |
| | Males | | Females | |
| Dosage level associated with animal numbers | Low Number | High Number | Low Number | High Number |
| | | | | |

| *In vitro* Study – Test Article | |
|---|---|
| a. Name of Article: | b. CAS No. |
| | c. LOT No. |
| d. Characteristics (strength, purity etc.): | e. Stability |
| | f. Source |

| *In vitro* Study – Control Article | |
|---|---|
| a. Name of Article: | b. CAS No. |
| | c. LOT No. |

| d. Characteristics (strength, purity etc.): | e. Stability |
|---|---|
| | f. Source |

| *In vitro* – Test and Control Articles | | | |
|---|---|---|---|
| a. Material Used to Solubilize or Suspend Articles: | c. Preparation Recipe | | |
| | Dosage Level | Grams Test Article | Grams Control Article |
| b. Route of Administration and Reason for Choice: | | | |

| *In vitro* Study – Test System *(insert additional rows placing the curser in the last column of the table, holding down the Alt key and pressing the A Key* | | | | | |
|---|---|---|---|---|---|
| a. Species | | b. Strain | | c. Substrain | |
| Name of Article | CAS No. | Lot No. | Purity | Source | Dosage |
| | | | | | |

## E. RATIONALE FOR ANIMAL USE

1) Explain your rationale for animal use: *[The rationale should include reasons why non-animal models cannot be used.]*

2) Justify the appropriateness of the species selected. *[The species selected should be the lowest possible on the phylogenetic scale.]*

3) Justify the number of animals to be used. *[i.e. the minimum number required to obtain statistically valid results.]*

## F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES

Briefly explain the experimental design and specify all animal procedures. This description should allow the IACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. *If a specific section is not applicable to the study please indicate with N/A.*

Specifically address the following:

1. **Animal Identification** (cage card, ear tag, etc.):
2. Animal Housing (provide justification for single housing):
3. **Animal Husbandry** (housing, feeding, bedding, water, etc.):
4. Maximum time individual animals will be in the vivarium (duration of greater than 90 days requires inclusion in the sentinel animal program):
5. **Experimental injections or inoculations** (substances, e.g., infectious agents, adjuvant, etc.; dose, sites, volume, route, and schedules):
6. **Blood withdrawals** (volume, frequency, withdrawal sites, and methodology):

**Veterinary assistance required:** ☐ **Yes** ☐ **No**

**Animal Husbandry (AHU) assistance required:** ☐ Yes ☐ No

7. **Radiation** (dosage and schedule):
8. **Methods of restraint** (e.g., restraint chairs, collars, vests, harnesses, slings, etc.). *(Include how animals are restrained for routine procedures like blood withdrawals. Prolonged restraint must be justified with appropriate oversight to ensure it is minimally distressing. Describe any sedation, acclimation or training to be utilized):*
9. **Food or water restrictions and justification:**
10. **Enrichment restrictions** (*Environmental enrichment is available for all research animals in the CFSAN program.* ***Food as enrichment will no longer be used in the CFSAN Animal Program.*** *Other environmental enrichment available include:* For Ferrets: *Tunnels, Non-edible Nylabones,* For Rabbits: *Dumbbells, Jingle Balls, Stainless Steel or Plastic Chains, Rabbit Shine Mirror, Plastic Play Apple,* For Rodents: *Non-edible Nylabones, Mouse Tunnels, Fast-Trac Hunt, Crawl Balls, Nestlets (not provided to nude rodents), Shepherd Shacks, Mouse Igloo,* For Guinea Pigs: *Dumbbell, Guinea Pig Hut*).
11. **Other procedures:** (e.g., (b) (4) studies, tail biopsies, etc.)
12. **Veterinary assistance required for procedure(s):** ☐ Yes ☐ No
    **List Procedure(s):**
13. **AHU assistance required for procedure(s):** ☐ Yes ☐ No
    **List Procedure(s):**
14. **Resultant effects, if any, that the animals are expected to experience** (e.g., pain or distress, ascites production, etc. If body weight loss is listed, it must be monitored throughout the entire study; body weight loss of 10% or more must **immediately** be reported to the Veterinary Staff):
15. **Other potential stressors** (noxious stimuli, environmental stress) **and procedures to monitor and minimize distress**: *(If a study is USDA Classification E, indicate any non-pharmaceutical methods to minimize pain and distress.)*
16. **Experimental endpoint criteria:** *(e.g., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. If body weight loss is listed, it must be monitored throughout the entire study; body weight loss of 10% or more must* ***immediately*** *be reported to the Veterinary Staff).* List *the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.*
17. **Veterinary care:** (indicate desired plan of action in case of animal illness, e.g., initiate treatment, call investigator prior to initiating treatment, euthanize etc.)
18. **Statistical Methods:**
19. **SOPs specific to this protocol:** *(please attach). Do not include animal facility SOPs or SOPs not dealing directly with animal care and use unless required by the nature of the protocol.*
20. **Records to be Maintained:**

21. **Types and Frequencies of Tests, Analyses and Measurements:** *(attach SOPs if applicable)*. **Note:** For (b) (4) studies, a schedule for critical phases is added by "Amendment to Protocol" after protocol approval and before initiation of the study.

## G. SURGERY

**Surgery conducted as part of the study:** ☐Yes (complete section G.) ☐No (skip to section H.)

1. Identify and describe the surgical procedure(s) to be performed. Include preoperative procedures (e.g., fasting, analgesic loading), and monitoring and supportive care during surgery. Include the aseptic methods to be utilized:

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed and postoperative care provided (building and rooms)?

4. If survival surgery, describe postoperative care required, frequency of observation, and identify the responsible individual(s). Include detection and management of postoperative complications during work hours, after hours, weekends and holidays:

5. If non-survival surgery, describe how humane euthanasia is enacted and how death is determined:

6. Are paralytic agents used during surgery? If yes, please describe how ventilation will be maintained and how pain will be assessed:

7. Has major survival surgery been performed on any animal prior to being placed on this study? [Major survival surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic functions (such as laparotomy, thoracotomy, crainotomy, joint replacement, or limb amputation).] If yes, please explain:

8. Will more than one major survival surgery be performed on an animal while on this study?

   If yes, please justify:

## H. PAIN OR DISTRESS CLASSIFICATION AND CONSIDERATION OF ALTERNATIVES

**A.** Pain or Distress Classification

Not all animals assigned to a study will fall into the same classification. For example, control animals in a category E study should not be assigned to category E in this section. Please assign animals to the proper pain code based on the experimental design, not the pain code designation for the entire study.

| **Species** (common name) | **USDA Classification*** **B, C, D or E** | **Number of animals used each year** | | | **3 year total number of animals** |
|---|---|---|---|---|---|
| | | **Year 1** | **Year 2** | **Year 3** | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| **Total number of animals (should equal total from Section B):** | | | | | |

*** USDA Classifications and Examples**

**Classification B:** Animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery, but not yet used for such purposes.

**Classification C:** Animals upon which teaching, research, experiments, or tests will be conducted involving no pain, distress, or use of pain-relieving drugs.

**Classification D:** Animals upon which experiments, teaching, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs will be used.

**Classification E:** Animals upon which teaching, experiments, research, surgery, or tests will be conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs will adversely affect the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

**Examples:**

- Procedures producing pain or distress unrelieved by analgesics such as (b) (4) studies, microbial virulence testing, radiation sickness, and research on stress, shock, or pain.
- Surgical and postsurgical sequella from invasion of body cavities, orthopedic procedures, dentistry or other hard or soft tissue damage that produces unrelieved pain or distress.
- Negative conditioning via electric shocks that would cause pain in humans.

**NOTE REGARDING CLASSIFICATION E:** An explanation of the procedures producing pain or distress in these animals and the justification for not using appropriate anesthetic, analgesic or tranquilizing drugs must be provided. This information is required to be reported to the USDA, will be available from USDA under the Freedom of Information Act, and may be publicly available through the Internet via USDA's website.

## Explanation for USDA Classification E

(This report is required to accompany USDA Form 7023 to support any USDA Classification E listings.)

This document must be typed.

Name of investigator:

Animal Study Protocol Title:

Species and number of animals listed in Classification E for each year:

Species:
Number of animals:
year 1 -
year 2 -
year 3 -
Total:

Description of project including reason(s) for species selection:

Provide a scientific justification to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressing procedures is contraindicated:

_____ _____

Signature of Investigator: Date:



_____ _____

Signature of IACUC Chairperson: Date:

B. Consideration of Alternatives and Literature Search

If any procedures fall into USDA's Classification D or E, causing more than momentary or slight pain or distress to the animals, describe your consideration of alternatives and your determination that alternatives are not available. Describe your rationale for determining that this work has not already been done. A minimum of two (2) databases must be utilized for the literature search.

**a. Delineate the methods and sources used in the search.**

**b. Alternatives include methods that (1) refine existing tests by minimizing animal distress, (2) reduce the number of animals necessary for an experiment, or (3) replace whole-animal use with in vitro or other tests. When ascites production is used to produce antibodies, justification needs to be given as to why *in vitro* systems cannot be used.**

## I. ANESTHESIA, ANALGESIA, TRANQUILIZATION, OTHER AGENTS

For animals indicated in Section H.1., Pain Code Classification D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration. Describe tracking and security of controlled drugs.

## J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY

| Indicate the proposed method of euthanasia. If a chemical agent is used specify the dosage and route of administration. If the method(s) of euthanasia include those not recommended by the AVMA Panel Report on Euthanasia (e.g., decapitation or cervical dislocation without anesthesia), provide scientific justification why such methods must be used. Indicate the method of carcass disposal if not described in Section K below. Describe tracking of controlled drugs. |
| --- |
| |

## K. SAFETY and SECURITY

Please indicate Y for yes or N for No to the following:

| Hazardous Agent | Yes | No | N/A | Agent(s)/Material(s) |
|---|---|---|---|---|
| Radionuclides | | | | |
| RSC approval attached | | | | |
| Biological Agents | | | | |
| Hazardous Chemicals or Drugs | | | | |
| Recombinant DNA | | | | |
| Select Agents | | | | |
| Material Safety Data Sheet (MSDS) Attached | | | | |
| Other *(i.e. carcinogens)* | | | | |

Study Conducted at Animal Biosafety Level: 1 ☐ 2 ☐ 3☐

| Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. |
| --- |
| |

| Describe any security practices and procedures associated with this study *(i.e. security plans for work with select agents)*. |
| --- |
| |

## L. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY

| List any special housing, equipment, animal care (e.g., special caging, water, feed, or waste disposal, environmental enhancement, containment etc.). Contact the facility manager/veterinary staff/animal husbandry project officer for availability of specialty items for the study. Specialty items may need to be purchased by the PI. |
| --- |
| |

## M. TRANSPORTATION

| Transportation of animals must conform to all institutional guidelines/policies and federal regulations. If animals will be transported on public roads or out of state, describe efforts to comply with USDA regulations. If animals will be transported between facilities, describe the methods and containment to be utilized. |
| --- |
| |

## N. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS

(e.g., cell lines, antiserum, etc.)

Biological Material/Animal Products: ☐Yes (complete section N) ☐No (skip to section O).

1. Specify Material:

2. Source: Material Sterile or Attenuated: ☐ Yes ☐ No

If derived from rodents, has the material been MAP/RAP/HAP tested*? [MAP - Mouse Antibody Production; RAP - Rat Antibody Production; HAP - Hamster Antibody Production]*

☐ Yes (Attach copy of results) or ☐ No

1. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

☐ **Initials of Principal Investigator**

## O. TRANSGENIC AND KNOCKOUT ANIMALS

| Describe any phenotypic consequences of the genetic manipulations to the animals. Describe any special care or monitoring that the animals will require. |
| --- |
| |

**P. Support Protocols (provide copies of each support protocol).**

☐ **Pathology Protocol**

☐ **Analytical Chemistry Protocol**

☐ **Clinical Chemistry Contract or Protocol**

☐ **Hematology Contract**

☐ **Other (explain)**

## Q. PRINCIPAL INVESTIGATOR CERTIFICATIONS

1. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
2. I certify that the individuals listed are authorized to conduct procedures involving animals under this proposal, have training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); and procedures for reporting animal welfare concerns.
3. For all USDA Classification D and E proposals (see section H.1.): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
4. I certify that I will obtain approval from the IACUC before initiating any significant changes in this study.
5. I certify that I will notify the IACUC regarding any unexpected study results that impact the animals. Any unanticipated pain or distress, morbidity or mortality will be reported to the attending veterinarian and the IACUC.
6. I certify that I am familiar with and will comply with all pertinent institutional, state, and federal rules and policies.

| | |
|---|---|
| **Principal Investigator/ Study Director:** ***(print name)*** | |
| | |

| | |
|---|---|
| **Signature:** | |
| **Date:** | |

**SIGNATURES:** ***(protocol will not be reviewed by the IACUC until supervisory, safety and responsible official (if applicable) signatures are obtained).***

| | |
|---|---|
| **Supervisor:** | **Date:** |
| **Division Director:** | **Date:** |
| **Office Director:** | **Date:** |
| **Safety Officer:** | **Date** |
| **Select Agent Responsible Official or Alternate (if select agent protocol)** | **Date** |

| | |
|---|---|
| | |
| **IACUC Chairperson** | **Date** |

## APPENDIX 1

### TRAINING AND EXPERIENCE RECORD FOR ANIMAL PROCEDURES

1. **Provide a completed form for each individual listed on the protocol that will be handling animals.**
2. **Each procedure must be listed individually by species.**
3. **Provide only experience with animal species pertinent to the study.**

**Name:**

**Protocol:**

**ABSL-3 Training** (if applicable): ☐ Yes Year:
☐ No

**Select Agent Training** (if applicable): ☐ Yes Year:
☐ No

*(Insert additional rows by placing the curser in the last column of the table, holding down the Alt Key and pressing the C Key)*

| Procedure | Species | Type of Training (hands on, observed, classroom, etc) | Trained by (Veterinarian, PI, AHU, etc.) | Time (in years) performing procedure | Performed the procedure in the past 3 years? (yes/no) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

## Appendix 2

**TRAINING REQUESTS**

1. **Provide any training requirements for individuals on the protocol.**
2. **Only one form needs to be submitted per protocol, multiple training needs and study personnel can be listed on a single form.**
3. **Once training is completed submit the signed training form to the IACUC chairperson**

List any training needs for individuals listed on the protocol (Insert additional rows by placing the curser in the last column of the table, holding down the Alt Key and pressing the **D** Key).

| Name | Procedure(s) | Training requested from veterinary staff, PI, other (specify) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Training provided by:

Printed Name

Signature

Date:

| Department of Health and Human Services<br>Public Health Service<br>Food and Drug Administration<br>Center for Food Safety and Applied Nutrition<br><br>**CFSAN -- AMENDMENT TO PROTOCOL** | BFQ NUMBER<br>AMENDMENT NUMBER<br>CLASSIFICATION OF STUDY<br>GLP Non-GLP |
|---|---|
| 1. PROTOCOL TITLE | |
| 2. TYPE OF CHANGE *(Check one)*<br>☐ Correction ☐ Addition ☐ Deletion ☐ Transfer | |
| 3. SECTION OF PROTOCOL AMENDED | |

| 4. REASON FOR AMENDMENT | |
|---|---|
| 5. DESCRIPTION OF CHANGE | |
| 6. SIGNATURE OF PRINCIPAL INVESTIGATOR | 7. DATE |
| 8. SIGNATURE OF DIVISION DIRECTOR (Optional) | 9. DATE |
| 10. SIGNATURE IACUC CHAIR | 11. DATE |

**FORM FDA 3244a (7/03)**

# Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES** Public Health Service

Food and Drug Administration
8301 Muirkirk Road
Laurel; MD 20708

Date: June 13, 2018

From: CFSAN Institutional Animal Care and Use Committee

Subject: Semi-annual Facility Inspection and Program Review

To: Institutional Official, CFSAN Institutional Animal Care and Use Committee

This represents the first semi-annual report for calendar year 2018 from the Institutional Animal Care and Use Committee (IACUC) of the Center for Food Safety and Applied Nutrition (CFSAN), as required by the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* (PHS Policy) and as a condition of continued accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC), International.

Members of the IACUC conducted the semi-annual evaluation of the CFSAN Animal Care and Use Program on April 17, 2018, using the 8th edition of the *Guide for the Care and Use of Laboratory Animals* (*The Guide*), as applicable. The Office of Laboratory Animal Welfare (OLAW) Sample Semi-annual Program Review Checklist was used to assist in the evaluation of the program. The annual program review was performed by the following committee members: (b) (5)

Guests included (b) (5) and Ms. Brenda Mitchell (QA/CFSAN).

Evaluation of the Animal Care and Use Program

1. IACUC Membership and Functions
   a. The IACUC is properly constituted.
2. IACUC Records and Reporting Requirements
   a. A copy of the minutes for the monthly IACUC meetings, protocols and associated correspondence, and semi-annual reports are present in the IACUC master files.
3. Veterinary Care:
   a. Clinical care is provided to the MOD-1 facility by (b) (5) including clinical care for the Gulf Coast Seafood Laboratory. (b) (5) will arrange for specialty care if required.
   b. Clinical care is provided to the Moffett Center Mouse Facility through an agreement with (b) (5) a veterinarian employed by Rush University Medical Center.
4. Animal Care Personnel
   a. The Animal Husbandry contract with Priority One Services provides service to the MOD-1 animal facility. (b) (5) LATG certified, is the project manager. (b) (5) serves as the Contract Officer's Representative (COR) for the Priority One Services Contract.
   b. The Principal Investigators (PIs) and study personnel provide animal care at the Gulf Coast Seafood Laboratory (GCSL) and the Moffett Center Animal Facility (MCAF).
5. IACUC Training: IACUC members (b) (4) ) attended (b) (4) . (b) (5) attended (b) (4) IACUC annual meeting in Columbus, OH on March 20 & 21, 2018, and a PRIM&R webinar: Building an Exceptional Animal Care and Use Program Through Engaged Leaders and Continuous Improvement on April 18, 2018.
6. Researcher and AHU Staff training is documented in Table 2.

7. Occupational Health and Safety of Personnel:
    a. An outside contractor has been hired to provide respirator fit testing for all government personnel and Oak Ridge Institute for Science and Education (ORISE) contractors at MOD-1 that are required to wear a respirator in the animal facility. The fit testing protocol is OSHA 29CFR1910.34. The fit testing method is QNFT using TSI PortaCount. Respirator fit testing for contractor personnel is provided through their respective companies. Respirator fit testing was done April 4-5, 2018.
    b. The MOD-1 Health Unit continues to provide all government employees on the Muirkirk Road Campus exposed to animals with the opportunity to enroll in the Occupational Health Surveillance Program.
    c. The Moffett Center has developed an Injury and Illness Prevention Plan and has an agreement with the local occupational health provider, EXCEL, to provide medical care.
    d. Medical care is provided to the GCSL personnel through an Interagency Agreement with the Army Corps of Engineers in Mobile, Alabama.
    e. The Animal Husbandry Unit (AHU) Priority One Personnel and the Mission Critical Support Services (MCSS) contract employees are required to have an annual physical and supporting laboratory tests through their respective companies.
8. Disaster Planning and Emergency Preparedness:
    a. The emergency plan is in place.
9. Aseptic Surgery:
    a. No survival surgeries are currently being performed at MOD-1.

**Inspection of the Gulf Coast Seafood Laboratory**

(b) (5) (IACUC member) and Dr. (b) (5) (PI) conducted an inspection of the Aquaculture facility at the Gulf Coast Seafood Laboratory (GCSL) on April 12, 2018. No deficiencies were found. There are no vertebrate or invertebrate animals in the facility at this time.

**Inspection of the Moffett Center Animal Facility (MCAF)**

Semi-Annual Inspection of Moffett Center Animal Facility (MCAF) was conducted on April 19, 2018 by (b) (5), FDA (MCAF Manager, IACUC member) and Viviana Loeza, IIT (Lab Tech).

Rm 409 – Animal Holding Room – No mouse activity since March 2010 at time of AAALAC Inspection. Room is orderly. Temperature and Humidity checked daily.

Rm 411 – Animal Procedure Room – No mouse activity since March 2010. Lab is clean and orderly. Hoods are working and certified. Freezer for storage of dead mice is empty and clean.

Rm 412 – Location of Cage Washer – Dishwasher is clean and orderly.

Rm B100 – Supply Storage – area clean and orderly. Supplies kept in sealed plastic bins.

MCAF SOP Review – conducted in January 2016. Revisions to SOP's in process as of this inspection.

**Inspection of the MOD-1 Animal Facility**

The MOD-1 facility inspection was conducted on April 18, 2018 by IACUC members (b) (5) . There were no animals present during the inspection. All deficiencies observed in the MOD-1 vivarium are considered minor and are summarized in Table 1. For each deficiency, the IACUC will request that the responsible party provide a written response on the corrective action(s) taken and the date that the corrective action(s) was taken. All corrective actions should be completed prior to the next inspection scheduled in October 2018. Corrective actions will be confirmed by a member of the IACUC. In the event that the appropriate correction cannot be accomplished in the allotted time, the response from the responsible party must include a short-term temporary solution and a long-term permanent solution with a specified time of completion. All deficiencies identified in the previous facility inspection were corrected.

**Minority Views:** None

# Appendix 10: IACUC/OB Periodic Report

**Table 1: Deficiencies in the MOD-1 Vivarium**

| Correction of the following deficiencies is the responsibility of Facilities. These deficiencies were first reported during the semi-annual inspection conducted on April 17, 2018. The estimated completion date is October 16, 2018. | | | | | |
|---|---|---|---|---|---|
| **Room** | **Deficiency** | **Major (check if yes)** | **Action/Notes** | **Completion Date** | **IACUC Verification** |
| G215 | The floor is showing several small raised areas | | Repair floor | In progress<br>Consulting with the Vendor | 10/24/2018 |
| G222 | Debris on floor in Receiving Bay area | | Sweep debris from the Receiving Bay floor | 5/7/2018 | 10/24/2018 |
| G602 | Holes in floor | | Repair holes in floor and repaint | 10/05/2018 | 10/24/2018 |
| G701 | The floor is showing several small raised areas; Split seam in ceiling | | Repair floor and re-caulk split seams in ceiling | In progress<br>Consulting with the Vendor<br>Ceiling repaired | 10/24/2018 |
| G701C | Chipped paint on door frame | | Prime and paint chipped paint area | 10/09/2018 | 10/24/2018 |
| G703 | Metal supports on the wooden benches are rusty | | Sand, prime and paint the metal supports on the wooden benches | 10/09/2018 | 10/24/2018 |
| G705 | Metal supports on the wooden benches are rusty | | Sand, prime and paint the metal supports on the wooden benches | 10/09/2018 | 10/24/2018 |
| Ground Floor Supply | | | | | |

# Appendix 10: IACUC/OB Periodic Report

| | | | | | |
|---|---|---|---|---|---|
| **Corridor** | | | | | |
| **G601** | **Crack in CMU wall near door frame to room G601** | | **Repair crack in CMU wall near door frame to room G601** | **10/12/2018** | **10/24/2018** |
| **Common use corridor** | **Crack in CMU wall near the double doors to the outside common use corridor** | | **Repair crack in CMU wall near the double doors to the outside common use corridor** | **10/12/2018** | **10/24/2018** |
| **G602** | **Chipped paint area on the door frame to room G602 by Autoclave #8** | | **Prime and paint chipped paint area on the door frame to room G602 by Autoclave #8** | **10/12/2018** | **10/24/2018** |
| **Ground Floor Return Corridor** | | | | | |
| **1403** | **Metal supports on the wooden benches are rusty** | | **Sand, prime and paint the metal supports on the wooden benches** | **10/10/2018** | **10/24/2018** |
| **1405** | **Metal supports on the wooden benches are rusty** | | **Sand, prime and paint the metal supports on the wooden benches** | **10/10/2018** | **10/24/2018** |
| **1501** | **Chipped paint on door** | | **Clean, prime and repaint chipped paint** | **10/10/2018** | **10/24/2018** |
| **1503** | **Chipped paint on door** | | **Clean, prime and repaint chipped paint** | **10/11/2018** | **10/24/2018** |
| **Unoccupied Rooms** | | | | | |
| **1614** | **Vent cover was not secured, paint chips on door frame** | | **Secure vent cover; prime and paint chipped paint on door frame** | **10/11/2018** | **10/24/2018** |
| **1616** | **Vent cover was not secured** | | **Secure vent cover** | **10/12/2018** | **10/24/2018** |
| **1617** | **Room was “under construction”, insect trap was last checked November 7, 2017, rust stains on floor, rust overhead on sprinkler** | | **Check/replace insect trap; clean rust stains on floor; clean off rust, prime and paint sprinkler** | **7/19/2018**<br>**10/4/2018** | **10/24/2018** |

# Appendix 10: IACUC/OB Periodic Report

| | | | | | |
|---|---|---|---|---|---|
| **1617a** | **Insect trap checked date was faded** | | **Replace insect trap** | **7/19/2018** | **10/24/2018** |
| **1618** | **Crack in wall near the door** | | **Fix crack in wall** | **10/04/2018** | **10/24/2018** |
| **1621a** | **Insect trap was checked September 2017** | | **Check/replace insect trap** | **7/3/2018** | **10/24/2018** |
| **1802** | **One light cover was not secured properly** | | **Secure light cover** | **10/04/2018** | **10/24/2018** |
| **1808** | **Paint chips on door frame** | | **Prime and paint chipped paint on door frame.** | **10/05/2018** | **10/24/2018** |
| **First Floor Supply Corridor** | | | | | |
| **1616** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/12/2018** | **10/24/2018** |
| **1801** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/12/2018** | **10/24/2018** |
| **1802** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/12/2018** | **10/24/2018** |
| **First Floor Return Corridor** | | | | | |
| | **Metal area beneath the first window in the BSL-3 Corridor is rusty** | | **Remove rust, prime and paint metal area beneath the first window in the BSL-3 Corridor** | **10/02/2018** | **10/24/2018** |
| **1827** | **Cracks in ceiling near room 1827** | | **Repair cracks in ceiling near room 1827** | **10/02/2018** | **10/24/2018** |
| | **Crack in the CMU wall in the BSL-3 corridor near the corridor entrance door from the Return Corridor** | | **Repair crack in the CMU wall in the BSL-3 corridor near the corridor entrance door from the Return Corridor** | **10/12/2018** | **10/24/2018** |

| | | | | | |
|---|---|---|---|---|---|
| | **The window frame area in the BSL-3 corridor is separating** | | **Caulk, prime and paint the window frame area in the BSL-3 corridor** | **10/12/2018** | **10/24/2018** |
| **1827** | **Chemical residue on top of doorframe to the entrance door to the room.** | | **Remove chemical residue from the top of the doorframe to the entrance door to the room** | **10/02/2018** | **10/24/2018** |
| | **Chipped paint on the door frame to the entrance door to the BSL-2/3 corridor.** | | **Prime and paint the door frame to the entrance door to the BSL-2/3 corridor** | **09/26/2018** | **10/24/2018** |
| **1201** | **Chipped paint on door frames** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **1614** | **Chipped paint on door frames** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **2619** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **2802** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **2805** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **2813** | **Chipped paint on door frame** | | **Prime and paint chipped paint area on door frame** | **10/02/2018** | **10/24/2018** |
| **Second Floor Return Corridor** | | | | | |
| **2610/2016** | **Chipped paint on CMU wall beneath the Phoenix Controls panel** | | **Prime and paint chipped paint area** | **10/02/2018** | **10/24/2018** |
| **2620** | **Crack in CMU wall near door frame to 2620** | | **Repair crack in CMU wall** | **10/02/2018** | **10/24/2018** |
| **General comments: In many rooms, signs on the eyewashes are posted as out of order and the eyewashes were found to be working. The signs need to be changed to indicate No Lab Activity (NLA).** | | | | | |

# Appendix 10: IACUC/OB Periodic Report

| Correction of the following deficiencies is the responsibility of Animal Husbandry. These deficiencies were first reported during the semi-annual inspection conducted on April 17, 2018. The estimated completion date is October 16, 2018. | | | | | |
|---|---|---|---|---|---|
| **Room** | **Deficiency** | **Major (check if yes)** | **Action/Notes** | **Completion Date** | **IACUC Verification** |
| 1512 | Necropsy room – Old Euthanasia SOP on file in room | | Replace with updated Euthanasia SOP | 4/18/2018 | 10/24/2018 |
| 1514 | Necropsy room – Old Euthanasia SOP on file in room | | Replace with updated Euthanasia SOP | 4/18/2018 | 10/24/2018 |
| 1603 | Expired quatricide spray bottle | | Replace quatricide | 4/18/2018 | 10/24/2018 |
| 1615 | The BD E-Z scrub was expired | | Replace the BD E-Z scrub | 7/19/2018 | 10/24/2018 |
| General comments: In many rooms, signs on the eyewashes are posted as out of order and the eyewashes were found to be working. The signs need to be changed to indicate No Lab Activity (NLA). | | | | | |

**Table 2. Researcher and AHU Technical Training**

| Date | Procedure | Attendees | Trainer |
|---|---|---|---|
| October 5, 2017 | Procedures for using Aims tattoo equipment | (b) (5) | (b) (5) |
| October 23, 2017 | FDA Safe Practices and Procedures for Animal Research | (b) (5) | CFSAN Staff College |

# Appendix 10: IACUC/OB Periodic Report

| | | | |
|---|---|---|---|
| November 1, 2017 | Zoonotic Diseases | (b) (5) | (b) (5) |
| December 14, 2017 | Sub-mandibular bleed, Gavage, Euthanasia | | (b) (5) |
| January 3, 2018 | Gas Anesthesia Machine Operation | | (b) (5) |
| January 11, 2018 | SOP Training | | (b) (5) |
| January 17, 2018 | Nail clip, Gavage | | (b) (5) |
| January 31, 2018 | Tattooing with video | | (b) (5) |
| February 8, 2018 | Intramuscular (IM) & Subcutaneous (Sub-Q) Injections | | |
| February 15, 2018 | Intraperitoneal (IP) and Intravenous (IV) Injections | | |
| February 20, 2018 | Cardiac Puncture/Cervical Dislocation | | |
| March 6, 2018 | Operation of Bottle Washer | | (b) (5) |
| April 3, 2018 | Operation of Rack Washers | | |
| April 10, 2018 | Operation of tunnel Washer # 1 | | |
| April 16, 2018 | Inventory: Training Room 2803 | | |
| April 17, 2018 | Operation of tunnel Washer # 2 | | |
| April 18, 2018 | Inventory: Room 21010 | | |
| April 18, 2018 | Morning Parameter Checks, 1st and 2nd floor return and supply sides | | |
| May 3, 2018 | Strategies for developing an institutional | | (b) (5) -Webinar |

# Appendix 10: IACUC/OB Periodic Report

| | | | |
|---|---|---|---|
| | program to manage compassion fatigue | | |
| May 11 & 14, 2018 | Morning Parameter Checks, ground floor return and supply sides | (b) (5) | (b) (5) |
| May 15, 2018 | Rat Tickling Webinar | | (b) (5) -Webinar |
| May 22, 2018 | Laboratory Animal Allergens and Other Allergies | | (b) (5) |

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

| **Location/Building/Facility:** | |
|---|---|

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

To be added

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution*. Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

[Create additional rows by pressing TAB in the bottom-right box.]

***Copy and repeat the Description and Table for each location, including all satellite housing locations.***

## *GCSL*

Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

| Room No. | Specific Use | Temperature Set-Point (define units) | Electronic / Emergency Monitoring of Temperatures (Y/N) | Alert/Alarm Temperature Ranges (if applicable; define units) | Humidity Control (Y/N) | Relative Pressure | Air Exchange Rate (per hour) | Date Verified / Measured |
|---|---|---|---|---|---|---|---|---|
| | | (settings to be verified) | | | | | (values to be measured) | |
| 118 | Animal Holding Room | 70°F | N | N/A | N | N/A | 10 | 10/29/18 |
| 119 | Surgery/Necropsy | 70°F | N | N/A | N | N/A | 10 | 10/29/18 |

[Create additional rows by pressing TAB in the bottom-right box.]

***Copy and repeat the Description and Table for each location, including all satellite housing locations.***

## *MOD-1 and Moffett Center To be added*

# Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist you in completing the form:

(1) List location of aquaria, including outdoor enclosures (ponds or outdoor tanks). If indoors, list building and room number. Note that all species housed at the same location and maintained via the same design and monitoring may be listed in the same row.
(2) Please indicate if embryonic (E), larval (L), juvenile (J) or Adult (A)
(3) Group tanks (ponds, outdoor tanks, multiple aquaria) are arranged as arrays with shared water supply; individual aquaria have exclusive water handling systems.
(4) Indicate water type, e.g., fresh, brackish, or marine.
(5) Indicate water pre-treatment, e.g., dechlorination, rough filters.
(6) Indicate water circulation, e.g., static, re-circulated, constant flow, or some combination of these. If applicable, indicate water exchange frequency and amount (percentage).
(7) Provide a key word for filtration employed, e.g., biological, chemical, mechanical, and type (e.g., mechanical-bead filter). A diagram may be provided showing the flow of water, filtration, source of "make-up" water and amount replaced daily.

**Part I**

| Location (1) | Species (2) | System Design | | | | | |
|---|---|---|---|---|---|---|---|
| | | Group / Individual (3) | Water Type (4) | Pre-treatment (5) | Circulation (6) | Filtration (7) | Disinfection (e.g., UV, ozone) |
| Animal Holding Room, 118 | finfish | Group | Fresh | None | Re-circulating | Biological, sand filter and charcoal | None |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

*Note:* Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

# Appendix 12: Aquatic Systems Summary – Part I

[Create additional rows by pressing TAB in the bottom-right box.]

# Appendix 12: Aquatic Systems Summary – Part II

The following key will assist you in completing this form:

(1) In these columns, please indicate monitoring frequency, e.g. daily, weekly, monthly or other point sampling frequency; continuous/real time, or none, if applicable. Also indicate method of control (heaters versus room HVAC, hand versus auto dosing, etc.).

(2) Indicate other parameters and their monitoring frequency, e.g., alkalinity, total hardness, conductivity, chlorine/chloramine.

**Part II**

| **Monitoring** *Indicate in the boxes below the frequency of monitoring and method of control for the following parameters. (1)* | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Location (from Part I)** | **Temperature** | **Salinity** | **pH** | **$NH_4$** | **$NO_2$** | **$NO_3$** | **Dissolved $O_2$** | **Total Dissolved Gases** | **Other. Please List (2):** |
| Animal Holding Room 118 | Daily | None | Daily | Weekly | Weekly | Weekly | None | None | Alkalinity and hardness, weekly |
| | | | | | | | | | |
| | | | | | | | | | |
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*Note:* This information may be provided in another format, provided that all requested data is included.

[Create additional rows by pressing TAB in the bottom-right box.]

# Appendix 13: Primary Enclosures and Animal Space Provisions

Please complete the Table below considering performance criteria and guiding documents (e.g., Guide, Ag Guide, ETS 123 and/or other applicable standards) used by the IACUC/OB to establish adequacy of space provided for all research animals including traditional laboratory species, agricultural animals, aquatic species, and wildlife when reviewing (b) (4) studies.

| Species | Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.) | Maximum Number Animals / Enclosure | Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other) | Enclosure Composition & Description** |
|---|---|---|---|---|
| Mouse | 11"X6.5"X5.0"<br>10"x6"x5" | 4 | *Guide* | standard polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops |
| Mouse | 11"X6.5"X5.0" | 4 | *Guide* | Individually Ventilated Cage |
| Mouse Breeding Pair | 16"X8.0"X8.0" | 2 | *Guide* | standard polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops |
| Mouse Trio Breeding | 12.0"X17.5"X8.0" | 3 | *Guide* | polycarbonate One Cage 2100 caging with a stainless steel wire lid and filter top |
| Rat | 17"x8.5x8"<br>16.0"X8.0"X8.0" | 1 | *Guide* | standard polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops |
| Rat Breeding Pair | 16.0"X8.0"X8.0" | 2 | *Guide* | standard polycarbonate shoebox caging with a stainless steel wire lid and micro-isolator filter tops |

# Appendix 13: Primary Enclosures and Animal Space Provisions

| Species | Dimensions of Enclosure (cage, pen, tank*, corral, paddock, etc.) | Maximum Number Animals / Enclosure | Guiding Document Used to determine the Institution's Space Standards (Guide, Ag Guide, ETS 123, Other) | Enclosure Composition & Description** |
|---|---|---|---|---|
| Guinea Pig | 17.5"X12.0"X8.0" | 1 | *Guide* | polycarbonate One Cage 2100 caging with a stainless steel wire lid and filter top |
| Rabbit | 5.2 sq. ft. with a cage height of 16.0" | 1 | *Guide* | plastic enclosures supported by a stainless steel frame, with floors designed to allow excreta to pass |
| Pigs | 20.0 sq. ft. | 1 | *Ag Guide* | enclosure flooring is a sheet composition vinyl with integral coves and welded seams, and the walls are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. Access to the animals is provided through a break resistant, clear access panel |
| Finfish | 60 in. diameter x 30 in. height | No more than 0.25 lb./gallon of water depending on the species | ILAR Journal Vol. 37 No.4 | 340 gallon circular fiberglass tanks with fiberglass and nylon net lids. Each unit is equipped with a water filtration system, and additional air stones. |

*For aquatic species, provide tank volume.
**Include descriptors such as open-topped, static microisolator, individually-ventilated cage systems (IVCS).

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

Please describe the cleaning and disinfection methods in the Table below. Note the washing/sanitizing frequency and method for each of the following:

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| **Micro-environment** | | | | |
| Solid-bottom cages (static) | Mechanical Washer | 2X per week | Bio-Det 800 | Communally housed mice |
| Solid-bottom cages (IVC) | Mechanical Washer | 1X per week | Bio-Det 800 | Mice |
| Suspended wire-bottom or slotted floor cages | Mechanical Washer | 1X per week | Bio-Det 800 | Rabbits |
| Cage lids | | | Bio-Det 800 | |
| Filter tops | Mechanical Washer | Monthly | Bio-Det 800 | Mice, rats, Guinea pigs |
| Cage racks and shelves | Wipe down with disinfectant, Mechanical Washer | Weekly, Quarterly, Bi-annually | Bio-Det 800 | All species, IVC |
| Cage pans under suspended cages | Mechanical Washer | 3X per week | Prepared with Bio-Strip 200 (for uric acid) | Rabbits |
| Play pens, floor pens, stalls, etc. | Hand washing/hose | Hosed daily and sanitized | PRL-18 (foam) | Pigs |
| Corrals for primates or outdoor paddocks for livestock | N/A | N/A | N/A | Not used |
| Aquatic, amphibian, and reptile tanks and enclosures | For 340 gallon holding tank – organic matter is scrubbed from tank surfaces using | At Study Completion | Sodium hypochlorite | GCSL |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| | brush and powdered cleanser before rinsing with tap water. The tank drain is closed and 1.5 gallons of full strength sodium hypochlorite is added, tank surfaces are scrubbed, and the tank is filled with water and pumps are used to circulate water for one (1) hour The effective chlorine concentration is >200 ppm. For the 75 gallon Living Stream tanks – discard the filter media and if seawater has been used, scrape away the barnacles/mussels and add 5 cups of sodium hypochlorite. Let stand for one (1) hour and rinse thoroughly with tap water and allow to dry before use. | | | |
| Feeders | Mechanical Washer | 1X per week,<br>3X per week,<br>1X per week,<br>1X per week | Bio-Det 800 | Rodents, Guinea pigs, Rabbits, Swine |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Watering devices | Mechanical Washer | 2X per week,<br>1X per week,<br>1X per week,<br>3X per week,<br>3X per week,<br>1X per week | | Communally housed rodents, Single housed rodents, Mice, Guinea pigs, Rabbits, Swine |
| Exercise devices and manipulanda used in environmental enrichment programs, etc. | Mechanical Washer/if item cannot withstand hot water item soaked in 10% bleach solution for 10 min. | 1X per week | 10% bleach soak | Mice, Guinea pigs, Rats, Rabbits, Swine |
| Transport cages | Mechanical Washer | After each use | Bio-Det 800 | |
| Operant conditioning & recording chambers, mechanical restraint devices (chairs, slings, etc.) | Hand cleaning | After each use | | |
| Euthanasia chambers | Hand cleaning | After each use | Quatricide PV 15 | |
| **Macro-Environment** | | | | |
| **Animal Housing Rooms:** | | | | |
| Floors | Hand washing | Daily | Quatricide PV 15 | MOD-1:Occupied animal rooms- |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| | | | | Unoccupied rooms are mopped quarterly deconned prior to introduction of animals |
| Walls | Hand washing | Quarterly | Quatricide PV 15 | MOD-1:Occupied animal rooms- Unoccupied rooms are mopped quarterly and deconned prior to introduction of animals |
| Ceilings | Hand washing | Quarterly | Quatricide PV 15 | MOD-1:Occupied animal rooms- Unoccupied rooms are mopped quarterly and deconned prior to introduction of animals |
| Ducts/Pipes | Hand washing | Quarterly | Quatricide PV 15 | MOD-1:Occupied animal rooms- Unoccupied rooms are mopped quarterly and deconned prior to introduction of animals |
| Fixtures | Hand washing | Quarterly | Quatricide PV 15 | MOD-1:Occupied animal rooms- Unoccupied rooms are mopped quarterly and deconned prior to introduction of animals |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Floors | Hand washing | Daily | Quatricide PV 15 | Moffett Center: Occupied animal rooms-<br>Unoccupied rooms are mopped prior to introduction of animals |
| Walls | Hand washing | Monthly | Quatricide PV 15 | Moffett Center: Occupied animal rooms-<br>Unoccupied rooms are sanitized prior to introduction of animals |
| Ceilings | Hand washing | Monthly | Quatricide PV 15 | Moffett Center: Occupied animal rooms-<br>Unoccupied rooms are sanitized prior to introduction of animals |
| Ducts/pipes | Hand washing | Monthly | Quatricide PV 15 | Moffett Center: Occupied animal rooms-<br>Unoccupied rooms are sanitized prior to introduction of animals |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Fixtures | Hand washing | Monthly | Quatricide PV 15 | Moffett Center: Occupied animal rooms-<br>Unoccupied rooms are sanitized prior to introduction of animals |
| Floors | Floor scrubber and/or high pressure water (if needed) | Study conclusion | Detergent | GCSL: Animal holding room |
| Walls | Hose down | Study conclusion | Fresh water | GCSL: Animal holding room |
| Ceilings | Dust ceiling tiles and wash the air handling outlets/vents | Study conclusion | | GCSL: Animal holding room |
| **Corridors:** | | | | |
| Floors | Hand washing | Quatricide PV 15 | Daily | MOD-1 |
| Walls | Hand washing | Quatricide PV 15 | Quarterly | MOD-1 |
| Ceilings | Hand washing | Quatricide PV 15 | Quarterly | MOD-1 |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Ducts/Pipes | Hand washing | Quatricide PV 15 | Quarterly | MOD-1 |
| Fixtures | Hand washing | Quatricide PV 15 | Quarterly | MOD-1 |
| **Support Areas (e.g., surgery, procedure rooms, etc.); complete for each area:** | | | | |
| Floors | Hand washing | Daily | Quatricide PV 15 | MOD-1: Necropsy Suite |
| Walls | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Necropsy Suite |
| Ceilings | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Necropsy Suite |
| Ducts/Pipes | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Necropsy Suite |
| Fixtures | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Necropsy Suite |
| Floors | Hand washing | Daily when in use; quarterly when not in use | | MOD-1: Surgery Suite |
| Walls | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Surgery Suite |
| Ceilings | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Surgery Suite |
| Ducts/Pipes | Hand washing | Quarterly | N/A | MOD-1: Surgery Suite |
| Fixtures | Hand washing | Quarterly | Quatricide PV 15 | MOD-1: Surgery Suite |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Floors | Floor scrubber and/or high pressure water (if needed) | Study Conclusion | Detergent | GCSL: Surgery |
| Walls | Hose down | Study Conclusion | Fresh water | GCSL: Surgery |
| Ceilings | Dust ceiling tiles and wash air handling outlets/vents and ducts | Study Conclusion | | GCSL: Surgery |
| **Implements (note whether or not shared):** | | | | |
| Mops | Mechanical Washer | Quarterly at a maximum | Bio-Det 800 | MOD-1: cleaning implements are not shared among animal rooms unless they have been disinfected before transfer |
| Mop buckets | Mechanical Washer | Quarterly at a maximum | Bio-Det 800 | MOD-1: cleaning implements are not shared among animal rooms unless they have been disinfected before transfer |
| Mops | Dedicated mops/scrub brushes for scrubbing floors; labeled for scrubbing tanks | Study Conclusion | Detergent | GCSL: only one fish room |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| | or floors; kept in separate locations | | | |
| Mop buckets | Dedicated/labeled "For scrubbing wet lab floors only" | Study Conclusion | Detergent | GCSL: only one fish room |
| Mops | Dedicated to animal facility | Study Conclusion | | Moffett Center: only one mouse room |
| Mop buckets | Dedicated to animal facility | Study Conclusion | | Moffett Center: only one mouse room |
| Aquaria nets | Dedicated nets for control (holding/control) tanks and Living Stream tanks (depuration tanks) | Washed or disinfected after each use | Isopropanol | GCSL: only one fish room |
| Floor Squeegee | Dedicated for drying floor | Study Conclusion | | GCSL: only one fish room |
| **Other:** | | | | |
| Vehicle(s) | Hose down bed/back of the pick-up with soap and water | Washed or disinfected after each | Soap and water | CGSL |
| Other transport equipment (list)<br><br>Flatbeds | Mechanical Washer | After each use<br><br>Quarterly at a | Quatricide PV 15 | MOD-1 |

# Appendix 14: Cleaning and Disinfection of the Micro- and Macro-Environment

| Area | Washing/Sanitizing Method (mechanical washer, hand washing, high-pressure sprayers, etc.) | Washing/ Sanitizing Frequency | Chemical(s) Used* | Other Comments (e.g., autoclaved) |
|---|---|---|---|---|
| Surgical Tables | | maximum | | |

Decon:
MOD-1
Activated Ionized Hydrogen Peroxide (Steramist-Decon)
Quatricide PV-15 (germicidal detergent use for Decon)

# Appendix 15: Facilities and Equipment for Sanitizing Materials

In the Tables below, summarize the facilities and equipment used to sanitize animal related equipment (tunnel washer, bottle washer, rack washer, bulk autoclave, hand-washing area, bedding dispensing unit, *etc.*). Note that some descriptions may be combined if all share identical features (e.g., all rack washers).

**[*Note*: Please remove the examples provided in the Table below.]**

| Building | Room No. | Equipment Type | Safety Feature(s) | Methods of Monitoring Effectiveness |
|---|---|---|---|---|
| MOD-1 | G-701 Supply side | Rack washer | Emergency "off" button; labeled exit door, de-energizing cord on both sides, instructional signage | Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly |
| MOD-1 | G-701 Supply side | Tunnel washer | Emergency "off" button; instructional signage | Guarantee 180-degree hot water rinse; temperature-sensitive tape used weekly; RODAC plates of caging tested quarterly |
| MOD-1 | G-701 Supply side #8<br><br>G-215 Return side #13 | Bulk autoclave | Emergency "off" button; lock-out key | ATP-based luminescence swabs performed quarterly |
| MOD-1 | G-215 | Bottle washer | Emergency "off" button | ATP-based luminescence swabs performed monthly |
| MOD-1 | Throughout AHU Facility | None – hand-washing area | Sinks and hand sanitizer | Visual assessment; RODAC plating of sanitized materials performed quarterly |

# Appendix 16: Lighting Summary

Using the Table below, summarize the lighting system(s) for the animal housing facility(ies). For each species or holding room type, list light intensity (range), construction features (e.g., water resistance), photoperiod (light:dark) and control (e.g., automatic versus manual, phasing). For systems automatically controlling photoperiod, describe override mechanisms (including alarms, if applicable).

| **Location**: | **MOD-1** |
|---|---|

**[*Note*: Please remove the examples provided in the Table below.]**

| **Room Type**[a] | **Light Intensity Range** | **Lighting Fixture Construction Features**[b] | **Photo-period** (hrs)[c] | **Photoperiod and Lighting Control** | **Override Mechanisms** (if applicable) |
|---|---|---|---|---|---|
| Rodent Holding Rooms | 130-300 lux | Surface mounted, water resistant | 10:14 | Automatic via building management system | Mechanical timer set at 30 minutes; recorded as "alarm" in building management system |
| Swine Holding Rooms | 300-400 lux | Surface mounted, water resistant | 12:12 | Automatic via wall-mounted timer box | Mechanical on/off switch |
| Surgery | 500 lux | Recessed, water resistant; arm-mounted, water resistant | NA | N/A | N/A |
| Necropsy | Not measured | Recessed, water resistant; arm-mounted, water resistant | NA | N/A | N/A |
| Cage-Washing Room | Not measured | Recessed, water proof | NA | N/A | N/A |
| GCSL Animal Holding Room, 118 | 124 – 1,000 lux | Surface mounted, water resistant | N/A | N/A | N/A |
| GCSL Surgery/necropsy, Room 119 | 1,900 | Surface mounted, water resistant | N/A | N/A | N/A |

Automatic light timer system in supply side hallways and motion detector system in the return side hallways.

# Appendix 17: Satellite Housing Facilities

*Note*: In the Program Description Section 2. IV. (Physical Plant), item C., describe the criteria used to determine a "Satellite Animal Holding Area." In the Table below, summarize these animal housing areas. Note that the total square footage for all each of these must also be included in the Summary of Animal Housing and Support Sites **(Appendix 2)**, and applicable information regarding these areas included in the Heating, Ventilation, and Air Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Systems Summary (**Appendix 16**).

| Building | Room(s) | Person Responsible | Species Used | Approximate Area ($ft^2$ or $m^2$) Devoted to Housing | Maximum Period of Stay | Purpose / Rationale / Justification | Construction Features and Finishes |
|---|---|---|---|---|---|---|---|
| GCSL | 118, 119 | R. Benner | Finfish | 8122 | 4-6 weeks | Acclimation, dose and depuration | The walls in the fish facility are heavy masonry (cement block) coated with block filler and two coats of epoxy paint. The ceilings consist of drop acoustic panels. The flooring is concrete with two coats of floor-grade epoxy paint (non-skid). There is no background noise other than the normal operation of the HVAC system and air/water filter/pump motors. Efforts are made by study personnel to minimize loud or sudden noise associated with routine procedures in the animal rooms. There is |

# Appendix 17: Satellite Housing Facilities

| Building | Room(s) | Person Responsible | Species Used | Approximate Area ($ft^2$ or $m^2$) Devoted to Housing | Maximum Period of Stay | Purpose / Rationale / Justification | Construction Features and Finishes |
|---|---|---|---|---|---|---|---|
| | | | | | | | not any vibration in the Wet Laboratory. Pumps are kept on short platforms made from pvc pipes and high-density polyethylene cutting board material (for absorbing vibrations) and do not vibrate the floor. |
| Moffett Center | 409, 411 | S. McDonald | Mice | 1081 | One week | | The floors of Rooms 409 and 411 are concrete and surfaced with epoxy flooring containing anti-skid texturing. Walls in the animal area are cement masonry units (cement masonry block) coated with block filler and two coats of epoxy paint. Ceilings in the animal rooms are double-layered drywall and are sealed at the walls and around light fixtures and air ducts. Interior |

# Appendix 17: Satellite Housing Facilities

| Building | Room(s) | Person Responsible | Species Used | Approximate Area ($ft^2$ or $m^2$) Devoted to Housing | Maximum Period of Stay | Purpose / Rationale / Justification | Construction Features and Finishes |
|---|---|---|---|---|---|---|---|
| | | | | | | | access doors are single-swing, 3 ft. wide and 7 ft. high. They are hollow steel doors with safety-wire vision panels and aluminum kick-plates. Exterior access doors are of stainless steel construction of the same design and dimensions. There are no exterior windows; however, the exterior doors have integrated safety-wire vision panels. |
| | | | | | | | |