

ANIMAL FACILITY BARRIER OPERATIONS (MOD I)

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ANIMAL FACILITY BARRIER OPERATIONS (MOD I)BARRIER TRAFFIC PATTERN

1. Purpose
 2. Background
 3. Procedures
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1. PURPOSE This Guide establishes CFSAN-wide procedures for entering and exiting the barrier at the MOD I animal facility.
 2. BACKGROUND The FDA animal facility known as Module I located at 8301 Muirkirk Road, Laurel Maryland is currently shared by researchers from the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Drug Evaluation and Research (CDER). In an effort to provide a suitable environment in which to conduct animal research, CFSAN in conjunction with CDER have agreed that the MOD I animal facility operate under a barrier system.
 3. PROCEDURES The following procedures are to be carried out to assure the integrity and protect the health of the animals involve in research conducted in CFSAN.
 - A. Entering the Barrier
 1. Access to the barrier is limited to those FDA and contract personnel who have been issued an approved security card administered by the Office of the Beltsville Technical Operations Staff. Visitors and unauthorized personnel will require the approval of the Animal Care Directorate (ACD) prior to entering the barrier.
 2. All persons who enter the barrier are required to wear protective clothing that will be available in the designated locker rooms. (See Guide 3008.02 - Barrier Clothing).
 3. Personnel shall enter the supply (clean) side of the barrier (color coded blue) from one of the locker rooms located on each floor.
 4. Materials and equipment that are required in the barrier must be sanitized prior to being transferred into the barrier through the Pass-through chamber adjacent to the locker rooms.

5. Personnel shall proceed to their work stations entering animal rooms only from the supply (clean) corridors.
6. All doors within the barrier must be kept closed except during the transit of personnel, animals, supplies and equipment.
7. Eating, drinking (with the exception of drinking water), smoking and storage of food for human consumption is not permitted in the barrier.

B. Exiting the Barrier

1. Generally, personnel are to exit the barrier via the return (dirty) corridor (color coded red). Disposable barrier clothing are to be placed in the designated receptacle located near the exit. Personnel wearing dedicated (cloth) barrier clothing must return to the locker room to deposit their clothing in the designated receptacle before exiting the barrier. However, there is a mechanism for leaving the barrier via the supply (clean) corridor if; (1) an animal room was never entered or (2) the shoe covers worn in the animal room are removed and replaced with new ones before leaving for the locker room by way of the supply corridor. The protective clothing worn shall be disposed of in the appropriate receptacle before exiting the barrier.
 2. Personnel who enter the return (dirty) corridor shall never re-enter an animal room or supply corridor without returning to the locker room for a complete change of barrier clothing.
 3. Equipment and materials including tissue samples shall be transported by way of the return corridor and transferred through the Pass-through chamber for removal from the barrier.
- C. Personnel working in the barrier shall be familiar with the requirements of specific ACD standard operating procedures that dictate barrier functions.

ANIMAL FACILITY BARRIER OPERATIONS (MOD I)

BARRIER PROTECTIVE CLOTHING

1. Purpose
2. Policy
3. Procedures

1. **PURPOSE** This Guide establishes the Center-wide procedures that outlines the kinds of protective clothing to be worn in the barrier at the MOD I facility.
2. **POLICY** CFSAN and contract personnel required to work in the barrier must wear appropriate protective clothing to minimize the potential for cross contamination and to protect the health of both the employee and that of the research animals housed in this facility.
3. **PROCEDURES**
 - A. All persons who enter the barrier are required to wear protective clothing provided in the locker rooms on each floor. Protective clothing include the following:
 1. Outer garment (disposable lab coat, disposable tyvek or cloth scrub suit)
 2. Disposable hair cover (bonnet)
 3. Disposable surgical masks
 4. Disposable shoe covers
 5. Disposable gloves
 - B. Additional protective measures (goggles, respirator, etc) for entry into study rooms shall be defined in study protocols that have been approved by the IACUC and Safety Committee. Such special requirements shall be posted on the study room door and are mandatory to be worn by all individuals who enter the study room.
 - C. Barrier protective clothing is not to be worn outside of the barrier except by those contract personnel whose duties require the movement of animals and supplies to and from the barrier (i.e. removal of trash, glassware and other material to areas outside of barrier and the receipt of animals from shipping bay, etc).

ANIMAL FACILITY BARRIER OPERATIONS (MOD 1)

ORDERING, RECEIPT AND ACCLIMATION OF ANIMALS

1. Purpose
2. Policy
3. Procedures

Attachment A - Form HHS-393, Purchase/Service/
Stock Requisition

Attachment B - Form FDA 3256, Animal Health
Certificate

1. PURPOSE This Guide establishes the Center-wide procedures for ordering and receiving animals to be used in research conducted in CFSAN.
2. POLICY The health status of all animals received at the MOD I facility must be determined prior to their introduction into the barrier and use in any study. The Senior Veterinary Medical Officer (SVMO) as a member of the Animal Care Directorate (ACD) shall review health status reports provided by proposed animal vendors in order to establish a list of approved vendors. Animals received from approved vendors will be acclimated in the assigned study room for the length of time stated in the protocol. Animals received from unapproved sources will be quarantined in one of the special purpose rooms on the ground floor for the period designated by the SVMO to determine health status for the species.
3. PROCEDURES
 - A. Ordering Animals
 1. The principal investigator/study director is responsible for ordering animals then coordinating and confirming the order and dates of delivery with the CFSAN Facility Manager to ensure that animal housing, care and feed accommodations are available for the animal delivery.
 2. Animal orders must contain complete specifications for the shipment.
 3. Animal deliveries shall be made Monday thru Friday during the facility's normal working hours, preferably 7:30 a.m. - 1:00 p.m.

B. Receipt of Animals

1. The shipping and receiving Unit of the Warehouse /Storerom Contractor will notify the Animal Husbandry Contractor when the delivery vehicle arrives.
2. The Animal Receiving Technician shall notify the SVMO and the principal investigator/study director of the arrival of the animal shipment. He will check the invoice against the purchase order (attachment A) for accuracy and completeness of the shipment. The accompanying documents are then signed and dated by the Animal Receiving Technician and the original of the document submitted to the principal investigator/study director with a copy retained by the Facility Manager.
3. The exterior of the shipment crates are sprayed with a disinfectant by Animal Care personnel before being transported to the designated animal room or to the special purpose room for uncrating.
4. SVMO or his designee shall make a visual observation of the animals for signs of disease, injury or stress. The animals shall be counted and the weight of some animals checked to determine the accuracy of the animal order.

C. Acclimation/Quarantine

1. The Animal Husbandry Contractor is responsible for providing animal care (i.e. feed, water, cleaning) during the acclimation/quarantine period.
2. After the acclimation/quarantine period has elapsed animals that appear to be in good health will be transferred to the principal investigator/ study director. The release record will be in the form of the Animal Health Certificate (Attachment B) signed and dated by the SVMO.

ANIMAL HEALTH CERTIFICATE

SHIPPED:
DATE _____ VENDOR _____ PURCHASE ORDER NO. _____

RECEIVED:
DATE _____ TIME _____ ROOM NO. _____
BY WHOM _____

DESCRIPTION:
SPECIES _____ STRAIN _____ NUMBER _____
WEIGHT _____ SEX _____

CONDITION OF ANIMALS: _____

QUARANTINE:
DATE IN: _____ DATE OUT _____ ROOM NO. _____
OBSERVATIONS _____

DIAGNOSTIC TEST(S) PERFORMED: _____

DISPOSITION: _____

STUDY DIRECTOR: _____ **PROJECT/NO.** _____

VETERINARY MEDICAL OFFICER
CENTER FOR FOOD SAFETY &
APPLIED NUTRITION
DATE _____

FORM FDA 3256 (9/86)

ANIMAL FACILITY BARRIER OPERATIONS (MOD-I)

REMOVING LABORATORY ANIMALS FROM THE BARRIER

1. Purpose.
2. Policy.
3. Procedures.

Attachment A - Animal Delivery Request Form

1. Purpose This Guide establishes the Center-wide procedures for removing research animals from the barrier to facility laboratories for terminal procedures.
2. Policy Occasionally there is a need for animals to be removed from the barrier for the purpose of performing procedures that cannot be carried out in the barrier but will result in the termination of the animals. Removal of animals from the barrier must be coordinated with the Research Facility Manager who will arrange for the packaging and transport of the animals to the laboratories by animal husbandry contract personnel. Animals may be kept in the laboratory for up to 12 hours but must not be kept unattended overnight and then be euthanized. No deliveries are to be made on weekends and holidays.
3. Procedures
 - A. Prior to the removal of animals from the barrier, the study director shall complete the Animal Delivery Request Form (Attachment A) and obtain the approval of an ACD representative (CFSAN Veterinarian or CFSAN Research Facility Manager).
 - B. The research Facility Manager will notify the Project Manager of the Animal Husbandry Contract of the request for animal transport from the barrier.
 - C. The animals will be placed in a polycarbonate cage system (cage, lid, top) with clean bedding for transport. If more than one box is needed a cart will be provided by the Animal Husbandry Contractor. The number of animals per cage will be in compliance with the requirements outlined in the N.I.H. Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act.
 - D. Animal Husbandry Contract personnel will note the disposition of the animals on the appropriate animal record.

- E. The traffic pattern for the transport of animals from the barrier will be via the return (dirty) corridor to the nearest exit for transfer to the laboratory by the study director.
- F. The study director is responsible for the appropriate labeling, packaging and transport of the animal carcasses from the laboratory to the storage freezer located in the incinerator room on the ground floor of the MOD-I facility.
- G. The study director is responsible for returning the used transport cages to the Animal Husbandry Contractor on the return (dirty) side of the cage washing area for sanitizing.

ACD SOP #8

ANIMAL DELIVERY REQUEST FORM

STUDY DIRECTOR: _____ TELEPHONE EXTENSION: _____
 PROTOCOL NUMBER: _____ ANIMAL ROOM NO.: _____
 DATE REQUEST SUBMITTED _____ ANIMAL SPECIES: _____
 DATE TRANSPORTED _____

TOTAL NUMBER OF ANIMALS REQUESTED: _____
 (Note: If animals have individual identification numbers, please include below.)

STRAIN	SEX	WEIGHT	AGE	ID	NUMBER REQUESTED

SPECIAL REQUIREMENTS: _____

DESIGNATED ALTERNATES WHO MAY TRANSPORT ANIMALS:

Approvals:

Study Director _____

Date _____

ACD Representative
 (CFSAN/CDER Veterinarian, CFSAN Facility Manager
 or CDER Research Coordinator)

Date _____

ANIMAL FACILITY BARRIER OPERATIONS (MOD-I)

USE OF THE EUTHANEX SYSTEM

1. Purpose
 2. Policy
 3. Procedures
-
1. Purpose This Guide establishes the procedures for the preferred method of euthanasia that is available for use by researchers in the Center for Food Safety and Applied Nutrition.
 2. Policy Individuals involved in animal research are required to utilize humane procedures when euthanizing animals. The Animal Care Directorate (ACD) and the Institutional Animal Care and Use Committee (IACUC) have approved the use of a method of euthanasia for small laboratory animals that is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Researchers who wish to use the Euthanex System must contact the Research Facility Manager for instruction on the proper use of the equipment.
 3. Procedures
 - A. The stationary Euthanex System is located in the necropsy room (Barrier) and is available to be used by those individuals scheduled to use the necropsy room. There is also a portable model that can be moved to various locations. Researchers shall contact the Manager of the Animal Husbandry Contract to arrange the use of the portable system. When there is a need to use the portable system outside the barrier (See Guide 3008.04) it is the responsibility of the researcher to coordinate the removal from and return to the barrier with the Manager of the Animal Husbandry Contract.
 - B. Researchers who use the portable Euthanex System are required to sanitize the unit according to the Animal Husbandry Contract SOP's prior to returning it to the barrier.
 - C. The operation of the Euthanex System is as follows.
 1. Place animal(s) in the polycarbonate cage with stainless steel lid.

2. Connect outlet line from the CO₂ and O₂ tanks to the nipple in the stainless steel lid.
3. Adjust the CO₂ mixture control valve and the flow rate control dial to the proper settings for the length of time required to induce euthanasia.
4. Close CO₂ and O₂ tank valves when procedure is complete.

ANIMAL FACILITY BARRIER OPERATIONS (MOD I)

CARE OF LABORATORY ANIMALS

1. Purpose
2. Policy
3. Procedures

1. **PURPOSE** This Guide establishes CFSAN wide procedures for the proper care and handling of all laboratory animals.
2. **POLICY** Animals involved in scientific research must be housed, handled and cared for in a manner that is consistent with the requirements of the Animal Welfare Act and the Public Health Service Guidelines. At MOD I, the animal husbandry services are provided by the Animal Husbandry Contractor whose duties include maintaining an environment conducive to the humane treatment of animals involved in scientific research. Although animal care services are available from the contractor, a researcher if he/she wishes, may perform the animal care on his/her study just as long as the standard operating procedures approved for use in the barrier are observed by the researcher.
3. **PROCEDURES**
 - A. Perform all animal husbandry and technical support duties according to approved, AHU standard operating procedures.
 - B. Sanitize all animal rooms prior to, during and at the completion of a study. Corridors and Elevators in the barrier area shall be swept and mopped daily (Monday-Friday).
 - C. Animals shall be provided clean cages, racks and bedding with the frequency of changes occurring at the intervals specified in approved SOPs or the study protocol.
 - D. Provide clean feed and water to laboratory animals, changing the feed cup and water bottle as frequently as required by the protocol. Assure that sufficient feed and water are available at all times for the animals whose intake is not restricted by protocol requirements.

- E. Animal equipment (cages, racks, litter pans, water bottles, feeder cups, etc) shall be removed, cleaned and transported to the animal room as indicated in approved SOPs. Dirty animal bedding and other waste materials are to be removed from the barrier on a daily basis (See QA Laboratory Manual Guide 3008.01 - Barrier Traffic Pattern).
- F. Perform observations of the general health of the laboratory animals on a daily basis. Moribund or dead animals observed are to be reported to the study director/principal investigator and the SVMO for disposition according to the protocol.
- G. Monitor the environmental condition (temperature, humidity, lighting, etc.) in the animal room daily. Report any facility problems to the Research Facility Manager and/or the study director.
- H. Provide technical duties such as weighing, injecting, gavaging, tissue excision, etc upon request of the study director/principal investigator.
- I. Deliver animals scheduled for necropsy to the necropsy room if required by study protocol.

ANIMAL FACILITY BARRIER OPERATIONS (MOD-D)

NECROPSY AND DISPOSAL OF ANIMALS

1. Purpose
2. Policy
3. Procedures

1. Purpose This Guide establishes the procedures for necropsy and animal disposal in a barrier environment.
2. Policy At the MODI facility the necropsy of animals must be conducted in one of the two suites designated for this purpose located on the first floor, return side of the barrier area. The only exception to this policy would be the need to remove animals from the barrier in order to perform laboratory test that cannot be conducted in the barrier environment that result in the euthanasia and subsequent necropsy of the study animals (See QA Laboratory Manual Guide 3008.04). Necropsies performed by the Pathology Staff are to take place in the suite designated for their use. The remaining suite is designated for community use and is to be used for the necropsy of animals not performed by the Pathology Staff. The Research Facility Manager and/or the Senior Veterinary Medical Officer will schedule the use of the necropsy suite on a first come, first serve basis. On the occasion when more than one study is to perform necropsies on the same date, the Research Facility Manager or the SVMO may be able to schedule the use of the Pathology necropsy suite if it is available.
3. Procedures
 - A. Study directors/principal investigators shall arrange for the use of the necropsy suite with the Research Facility Manager or the SVMO for the dates of the scheduled necropsies. No action need be taken if necropsies are to be performed by the Pathology Branch.
 - B. Animals scheduled for necropsy as well as needed supplies are to be brought to the necropsy suite by animal husbandry personnel via the return corridor.
 - C. Tissues are excised, weighed and collected according to the requirements of the approved protocol and standard operation procedures.

- D. The necropsy suite is usually available on an as needed basis for the necropsy of animals found dead or moribund. However, the study director shall contact the Research Facility Manager for access to the suite if the necropsy is not performed by the Staff Pathologist or the SVMO.
- E. Animal carcasses not submitted for necropsy shall be place in a sealed plastic bag and labeled "Dispose". Carcasses from necropsied animals shall be handled similarly, placed in the return corridor for pick-up by animal husbandry personnel according to approved Animal Husbandry Unit (AHU) standard operating procedures.