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Superseding
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National Institutes of Health Standard for Laboratory Animal Bedding Processing, Packaging and Facility Sanitation

1. PURPOSE AND SCOPE

This standard establishes the requirements in the following areas of laboratory animal bedding processing (1) raw material, manufacturing facility and warehouse sanitation (2) treatment for product processing and (3) product packaging.

2. APPLICATION

The standard is applicable to all laboratory bedding purchased under National Institutes of Health contracts, unless otherwise specified.

3. REQUIREMENTS

3.1 Plant Sanitation

- a. The Manufacturer shall have a written **Standard Operating Procedure (SOP)** for the maintenance and sanitation of the receiving, production, and storage areas. These SOP's shall provide, in detail, methods that are used to ensure these areas remain orderly, sanitary, properly maintained and pest free to comply with the standards herein. These SOP's shall also contain a schedule for the maintenance and sanitation of the aforementioned areas. A copy of these SOP's with the name and title of person(s) responsible for ensuring that these duties are performed shall be provided to the Government Inspector at time of inspection of the facility.
- b. To prevent contamination of raw materials and product, plant sanitation methods at a minimum shall include the following:
 - 1) Daily cleaning and removal of all loose raw material and debris from floors around production apparatus.
 - 2) Periodic removal of trash, dirt, and other debris lodged on floors, walls, I-beams, pipes, and ceilings of the production facilities and warehouses.

3.2 Pest Management

- a. The manufacturer shall have in place a documented effective integrated pest management program provided by a licensed pest control company. The pest control company shall adhere to all applicable local, State, and Federal regulations. The program shall consist of

regularly scheduled pest management services, including monitoring for pests (pests include invertebrate and vertebrate animals), and surveying facilities for conditions that promote pest activity. The program shall emphasize the use of non-chemical pest management methods such as traps, exclusion, harborage reduction, and strive to provide corrective actions/recommendations that will provide long lasting control while reducing pesticide usage. The manufacturer shall maintain accurate and complete records of all pest management activities and shall provide these records to the Government Inspector at the time of facility inspection.

- b. Manufacturing and product storage areas shall be effectively rodent and bird proofed. These areas shall be free of insects, rodents, and birds at all times.
- c. Pest management records shall be maintained in a log book and at a minimum contain the following sections:
 - 1) **Program Information** - this section shall contain pest management company contacts and service personnel information.
 - 2) **Client Pest Sighting-** this section is intended for facility personnel to record pest sightings and to communicate that to the pest management professional servicing the facility.
 - 3) **Pesticides** - this section shall include a list of primary pesticides to be applied at the manufacturing facility. A current copy of each pesticide label and MSDS, (material safety data sheets) shall be included in the order it was listed.
 - 4) **Facility Map** - a floor plan(s) shall be used to indicate the location of any type of pest management device. i.e., sticky trap, pheromone trap, light trap, rodent trap etc. used in the integrated pest management (IPM) program. The locations of pest control and monitoring devices shall be maintained and kept current.
 - 5) **Service Reports** - Pest management services performed at the facility shall be placed in this section. Service report records shall include but not be limited to:
 - a) Results of monitoring and inspections, including accepted common/generic names of all pests, numbers of each pest, and the location in the facility they were trapped or observed.
 - b) Pest sightings and conditions conducive to pest infestation shall be reported on pest management data sheets.
 - c) Specific written recommendations evaluating sanitation conditions, structural repairs i.e., caulking, sealing, and harborage reduction, as well as, operational changes that will prevent and/or reduce pest problems and enhance the effectiveness of the pest management program.
 - d) Include control products applied, the concentrations and quantities of all pesticides applied, including the accepted Environmental Protection Agency common names (generic names), method(s) of application, area of application in the feed mill, warehouse and other surrounding grounds.
- d. "Restricted Use" pesticide application will be undertaken by a certified pesticide applicator or licensed pest control contractor or under the direct supervision of same in accordance with label directions and local, State and Federal regulations.

- e. "General Use" pesticides, in states not requiring certification, may be undertaken by a person who has attended a pesticide seminar or been trained by a licensed applicator and who has demonstrated to have expertise and knowledge in the correct and safe use of pesticides or is under direct supervision of a Certified Pesticide Applicator. All applications shall be made in compliance with label directions.
- f. Outside bait stations designed for mouse and rat control using EPA registered rodenticide baits shall be tamper resistant, labeled, locked, and secured in place around the facility's perimeter. Bait station covers should be secured by material that cannot be easily severed.
- g. Internal measures for rodent control monitoring programs shall include devices, such as glue boards, mechanical traps, extended trigger traps, but not feeding stations.
- h. No domestic animals or fowl, wild animals or birds shall be confined in or have entry to building(s) housing production equipment, delivery site of and providing storage for feed ingredients or storage for the finished product. Provide, where necessary, effective screening or other protection against pests.
- i. The manufacturer shall have in place a program that discourages the nesting and lofting of nuisance birds and other feral animals on the exterior of buildings and on the grounds immediately surrounding the production and storage facilities which is controlled by the manufacturer.
- j. An exterior weed control program shall also be included in the pest management effort.

3.3 Manufacturing and Warehouse Facilities

- a. Facilities and manufacturing apparatus used for preparation of laboratory animal bedding shall not be used for manufacturing or storing of any products to which fertilizers, rodenticides, insecticides, hormones, germicides, bactericides, or fumigants have been added.
- b. Premises shall be dry, reasonably clean, and free of dirt, trash, animal and bird excreta and other foreign matter that could contaminate bedding being processed or stored. The premises is defined as the interior of the building and surrounding grounds controlled by the manufacturer.
- c. All structural beams, supports, and other structural systems that are painted shall be maintained in an appropriate manner to preclude or eliminate chipping, flaking, and peeling paint.
- d. Space should be provided for proper placement of equipment, storage of materials, and adequate aisles or work space between equipment and/or structures shall be maintained to allow for effective maintenance, cleaning, and pest management.
- e. Floors, walls, and ceilings shall be of such construction as to be adequately cleanable and kept in good repair.

- f. Fixtures, ducts, and pipes shall be installed in such a manner that drip or condensate does not contaminate raw materials and finished product.
- g. Lighting shall be provided in all areas to allow effective housekeeping, pest management, and bedding production. Light bulbs, fixtures, mirrors, skylights, or other glass suspended over raw material and product zones, and packaging areas shall be of the safety type or otherwise protected to prevent breakage.
- h. In wet processing areas floor drains with grates shall be installed, maintained, and operational. Floors in wet processing areas shall be maintained to allow proper drainage and prevent accumulation of water and debris.
- i. Rest room facilities shall be adequate and readily accessible to all personnel involved in the manufacture, storage, and transport of the laboratory animal bedding.
- j. Bags of laboratory animal bedding shall be stacked on pallets at least 18 inches away from the walls in order to facilitate cleaning, rotation, and pest management surveillance activities.
- k. To eliminate the potential for contamination of laboratory animal bedding, raw material, finished product, and packaging supplies shall not be stored in the same warehouse with products containing antibiotics, drugs, fertilizers, toxic chemicals, or any chemical compounds known to be undesirable. If this is not practical the bedding shall be stored at a minimum of 30 feet from any potential contaminant and written standard operating procedures describing how the bedding will remain segregated from potential contaminants must be provided to the Government Inspector for approval.

3.4 Production and Warehouse Facility Grounds

- a. The grounds surrounding the production and warehouse facilities under control of the operator shall be kept in a condition that will protect against the contamination of the raw materials and finished product. The grounds are defined as drive ways, parking lots, receiving, shipping, and storage areas and buildings.
- b. The bedding manufacturer shall have a SOP for the maintenance of grounds which shall include but are not limited to: properly storing equipment, removing litter and waste within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.

3.5 Equipment and Machinery

- a. Regulating and recording controls, thermometers, or other temperature measuring devices shall be installed and routinely calibrated on any equipment intended to insure product quality. The manufacturer is responsible for determining calibration schedule. Records of the calibrations shall be provided to the government inspector at the time of inspection.

- b. Maintenance records for the production equipment, scales, and regulating and recording controls shall be made available to the NIH inspectors at the time of inspection of the facility. All equipment shall be maintained and cleaned on a regular basis as determined by the bedding manufacturer. Maintenance and cleaning records shall be provided to the Government Inspector at the time of inspection.
- c. All equipment shall be so constructed and maintained as to prevent lubricants and coolants from becoming unsafe additives in raw materials or finished bedding.
- d. The manufacturer is required to have equipment (ie. Ro-tap or similar) that can insure the bedding particle size is in compliance with NIH specifications.
- e. The manufacturer is required to have equipment (ie. moisture balance) that can insure the bedding moisture is in compliance with NIH specifications.

3.6 Product Processing

- a. Decayed raw materials or raw materials that have been used for other purposes (i.e. used lumber) shall not be used in products covered by this standard.
- b. The raw material to be processed for animal bedding shall be free of bark, and all foreign materials.
- c. The product shall be processed in a closed system with the exception of aspirators which are necessary to control dust. This system shall include the following:
 - 1) Thermal Dryers, when needed, to reduce the inherent moisture content of the product and/or to control pathogenic bacteria. Unless otherwise specified in the applicable product specification, the laboratory animal bedding shall contain at least 6% but not more than 12% moisture (based on moisture removal by moisture determination balance) at the time of delivery. The air temperature at the exhaust vent of the dehydrator shall be a minimum of 180°F.
 - 2) Aspiration to decrease the amount of dust in the bedding. The product shall be subjected to aspiration during the manufacturing process. The aspiration shall decrease the dust content on the bedding to levels that will not inhibit in any way the normal respiratory process of laboratory animals reared on the bedding.
 - 3) Screening apparatus to standardize the particle size of the product. The bedding shall be screened so the minimum and maximum particle size is in accordance with the applicable product specification.
- d. The product shall be bagged immediately after the manufacturing process is completed. There shall be no bulk storage (with the exception of surge bins along the production line) of the finished product.

3.7 Packaging

- a. Bags, Paper: Paper bags shall be new and unused and shall be suitable for domestic shipments, handling, and covered storage. Paper bags shall be of at least two (2) wall

constructions with each wall fabricated of Kraft paper having a thickness of at least .006 inch. Inner wall shall be arranged within the outer walls in such a manner that each wall will bear its share of the burden. Bags shall be a square or box type construction and the overall size shall be commensurate with the maximum content specified, so that when filled, shall retain its square or box type construction and shall provide suitability for handling, palletizing and storage. The bottom or factory closed end shall be pasted. The top closure, after filling, may be sewn or pasted provided the square or box type construction is retained. The adhesive used in securing any pasted ends shall be such that it will prevent accidental opening when handled or transported. The use of a corrosive type staple and adhesive tape will not be acceptable. Bags may be factory closed on top and provided with a filling valve or tuck-in sleeve. The top closure method shall provide a securely held positive closure against sifting or spilling.

- b. Adhesive Toxicity: The adhesive used in the fabrication of the bags shall have no adverse or toxic effect on the contents of the bag prior to or when subjected to steam sterilization. The successful bidder may be required to furnish to the Contracting Officer a certificate stating that the adhesive used contains no known toxic material.
- c. Adhesive Resistance to Heat: The adhesive bond shall resist a maximum temperature of 250°F for a minimum period of one hour when bag and contents are subjected to sterilization by autoclaving.
- d. Marking: Each bag shall be clearly marked (either on the bag or via tag) with the appropriate nomenclature and NIH Stock Number as prescribed in the product specification. Other markings shall include the trade name of the product, the name and address of plant where manufactured, the net weight and the bag manufacturer's trademark or identification.

3.8 Transportation

- a. Railroad cars and trucks used to transport laboratory animal bedding shall be as free as is practical of dirt, trash and objects that could puncture paper bags.
- b. The vehicles shall be water tight and so constructed to prevent entrance of rodents, birds or insects.
- c. Laboratory animal bedding shall not be transported with products containing antibiotics or drugs, fertilizers or any chemical compounds known to be undesirable.
- d. Laboratory animal bedding shall not be shipped on pallets that are dirty, broken, contaminated with chemical compounds and/or pest feces, or that are contaminated with or harbor insects.

3.9 Inspection

- a. Product - Bedding shall be inspected for coarseness, splinters, slivers, bark, all foreign materials, sandings, dust, moisture content, packaging and marking.

- b. Facility - Prior to award of contract, or at any time during the effective period of the resulting contract, the contractor's plant, plant facilities, and milling operations will be subjected to inspection by authorized personnel of the National Institutes of Health. Failure to comply with the requirements of this standard shall constitute sufficient grounds for withholding contract award or for cancellation of existing contracts.