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National Institutes of Health Standard for Laboratory Animal Feed Processing and Mill Sanitation

1. PURPOSE AND SCOPE

This standard establishes sanitation, pest management, and quality assurance requirements applicable to the manufacture of laboratory animal feed, the facility wherein the feed is manufactured, and the premises wherein the feed ingredients and the finished products are stored and transported.

2. APPLICATION

Contracts for laboratory animal feed from commercial sources, wherein this standard is made a part either by direct or indirect reference, shall be limited to those sources complying with this standard.

3. REQUIREMENTS

3.1 Personnel

- a. Qualified personnel and adequate personnel training and supervision are essential for the proper formulation, and manufacture of laboratory animal feed. All employees involved in the production of laboratory animal feeds shall have an understanding of the manufacturing operations which they perform.
- b. The Manufacturer shall maintain employee training records pertaining to topics including but not limited to feed production, quality control, sanitation, maintenance, pest management, proper rotation of ingredients and product. These records shall be provided to the Government Inspector at time of inspection of the facility.

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 company shall be able to provide pest management training for feed manufacturer personnel and have the technical expertise to solve special pest problems.

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. 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 Siting** - 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) **Quality Assurance Reports** - This section shall contain program evaluation reports done by the pest control companies quality assurance personnel. Program evaluations shall be conducted at a minimum each quarter. This person shall not be the pest management technician.
 - 6) **Service Reports** - Monthly 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.
 - 7) **Educational Information** - This section should contain information about pests and procedures, as determined by the pest control company, that will help facility personnel better understand the pest management program. It shall serve as a reference for pests commonly found in and around the facility receiving the service.

- c. "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.
- d. "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.
- e. 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.
- f. Internal measures for rodent control monitoring programs shall include devices, such as glue boards, mechanical traps, extended trigger traps, but not feeding stations.
- g. No domestic animals or fowl, wild animals or birds shall be confined in or have entry to building(s) housing milling 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. All manufacturing and storage areas shall be effectively rodent and bird proofed.
- h. 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 feed production and storage facilities which is controlled by the manufacturer.
- i. An exterior weed control program shall also be included in the pest management effort.

3.3 Manufacturing and Warehouse Facilities

- a. Premises shall be dry, reasonably clean, and free of dirt, trash, animal and bird excreta and other foreign matter that could contaminate feed being processed or stored. The premises is defined as the interior of the building and surrounding grounds controlled by the manufacturer.
- b. 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.
- c. 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.
- d. Floors, walls, and ceilings shall be of such construction as to be adequately cleanable and kept in good repair.

- e. Fixtures, ducts, and pipes shall be installed in such a manner that drip or condensate does not contaminate foods, raw materials, or food-contact surfaces.
- f. Lighting shall be provided in all areas to allow effective housekeeping, pest management, and feed production. Light bulbs, fixtures, mirrors, skylights, or other glass suspended over ingredient and product zones, and packaging areas shall be of the safety type or otherwise protected to prevent breakage.
- g. 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 offal.

3.4 Production and Warehouse Facility Grounds

The grounds about the feed production and warehouse facilities under control of the operator shall be kept in a condition that will protect against the contamination of feed. The grounds are defined as drive ways, parking lots, receiving, shipping, and storage areas and buildings. The feed manufacturer shall have a SOP for the maintenance of grounds which shall include but are not limited to:

- a. 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.
- b. Adequately draining areas that may contribute contamination to feed and ingredients by seepage, foot-borne filth, or providing a breeding place for pests.
- c. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where feed and ingredients are exposed.

3.5 Equipment and Machinery:

- a. To prevent contamination of feed the production of laboratory animal feed shall be accomplished in a closed system where ever practical. Feed ingredients shall be transferred directly to the various milling apparatus inside pipes or elevators.
- b. Milling apparatus used to manufacture products containing additives such as rodenticides, insecticides, hormones, antibiotics, growth promoters, or fumigants shall not be used to manufacture laboratory animal feeds without prior written approval from the Contracting Officer. In order to obtain such approval, the feed contractor may be asked to provide: (1) details of the procedures designed to ensure the manufacture of uncontaminated feed or (2) reports of negative assays for the contaminant in question for each batch of feed manufactured for the National Institutes of Health. Under the latter option, the assay shall be conducted at no cost to the government.

- c. 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.
- d. All equipment shall be maintained and cleaned on a regular basis as determined by the feed manufacturer. Maintenance and cleaning records shall be provided to the Government Inspector at the time of inspection.
- e. All equipment, including scales and liquid metering devices, shall be of suitable size, design, construction, precision and accuracy for its intended purpose.
- f. All equipment shall be so constructed and maintained as to prevent lubricants and coolants from becoming unsafe additives in ingredients or feed.
- g. All equipment shall be designed, constructed, installed, and maintained so as to facilitate inspection and use of clean-out procedures.
- h. Feed and ingredient-contact surfaces shall be corrosion-free when in contact with feed and ingredients. They shall be made of non-toxic materials and designed to withstand the environment of their intended use and the action of feed, and if applicable cleaning compounds and sanitizing agents.
- i. Feed-contact surfaces shall be maintained to protect feed from being contaminated by any source.
- j. 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.

3.6 Operational Methods

- a. A formal preventive maintenance program shall be in use to prioritize identified structural, equipment, or utensil maintenance problems that could cause feed adulteration or affect feed quality.
- b. Bagged feed ingredients and finished products shall be stored in separate locations in well lighted clean warehouses to prevent possible contamination. The minimum separation between feed ingredients and finished laboratory animal feed shall be 20 feet or by a physical barrier.
- c. Bags shall be stacked on pallets at least 18 inches away from the walls in order to facilitate cleaning, rotation, and pest management surveillance activities.
- d. Feed ingredients, finished product, and packaging supplies shall not be stored in the same warehouse used to store products containing antibiotics, drugs, fertilizers,

cleaning supplies, toxic chemicals, or any chemical compounds known to be undesirable.

- e. Ingredients, finished product, and packaging supplies shall not be stored in the same warehouse with non-product related materials, such as parts and equipment.
- f. Proper rotation of all ingredients and packaging supplies shall be undertaken on a “first-in, first-out” (FIFO) basis or other verifiable methods to ensure stock rotation.
- g. All outside receiving lines or caps to both bulk dry or liquid ingredients shall be locked and identified.
- h. Transfer and Handling of Materials
 - 1) Containers shall be kept off the floor at all times and covered when not in use, and all ingredient storage containers shall be properly identified to maintain ingredient identity and traceability throughout usage.
 - 2) All materials selected for transport to processing areas shall be visually inspected and cleaned prior to transport.
 - 3) All in-use ingredient containers shall have individual transfer scoops. The use of a common scoop for use on multiple ingredients shall be strictly prohibited due to cross contamination.

3.7 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 ingredients and product, plant sanitation methods, at a minimum, shall include the following:
 - 1) Daily cleaning and removal of all loose feed material from floors around milling apparatus.
 - 2) Periodic removal of dirt, feed debris, fines, and offal lodged on floors, walls, I-beams, pipes, and ceilings of the production facilities and warehouses.
 - 3) Daily removal of all broken bags of ingredients or products from warehouse areas.
 - 4) Daily removal of bins of waste product from the production facilities.
 - 5) Insect-infested or rodent damaged ingredients or finished products shall be removed from the premises immediately after detection.
- c. All persons working in direct contact with laboratory animal feed, feed contact surfaces, and feed-packaging materials shall conform to hygienic practices while on duty to the

extent necessary to protect against contamination of feed. The hygienic practices shall be defined by the manufacturer in a standard operating protocol (SOP). The SOP will be provided to the Government Inspectors at the time of inspection. The methods for maintaining cleanliness shall include at a minimum:

- 1) Wearing clean uniforms in a manner that protects against the contamination of feed, feed-contact surfaces, or feed packaging materials.
 - 2) Maintaining adequate personal cleanliness.
 - 3) Washing hands thoroughly to protect against contamination with undesirable microorganisms in an adequate hand-washing facility at any time when the hands may have become soiled or contaminated.
 - 4) Confining the following to areas other than where feed may be exposed or equipment and utensils are washed: eating food, drinking beverages, and using tobacco.
- d. The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Water that contacts feed and feed-contact surfaces shall be sanitary and potable.
- e. Sewage disposal shall be made into an effective sewerage system or disposed of through other adequate means that prevents contamination of feed, feed contact surfaces, and water supplies.
- f. Employees shall be provided with clean readily accessible toilet and sink facilities.
- g. On a daily basis, rubbish and offal shall be so conveyed, stored, and disposed of as to minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of feed, feed contact surfaces, water supplies, and ground surfaces.

3.8 Quality Control of the Feed Manufacturing Process

The manufacturer shall define the feed manufacturing quality control process, including the performance schedule if not designated below. The manufacturer shall maintain records for the following quality control procedures, and shall provide these records to the Government Inspector at the time of inspection.

- a. Ingredient inventories shall be performed regularly by a designated employee to ensure that correct amounts of ingredients are being used to produce the lab animal feed. This can entail checking the actual yield for each batch of feed against the expected yield.
- b. Ingredient storage bins shall be inspected regularly and cleaned when needed.
- c. Critical parts of equipment that shall be examined frequently include: discharge gates and elevator boots cleaned and inspected for wear and leakage; elevator head pulleys checked for correct alignment, heat and wear; turnheads examined for correct position and wear, and; scalpers or ingredient cleaning equipment.

- d. Hammermill and/or grinding equipment condition and wear shall be checked daily. Magnets should be cleaned and checked for intended operation.
- e. Mixing- Batch mixers shall be examined regularly to ensure the shafts, ribbon paddles, or screws are in good repair and contain no buildup. Mixing times should be checked twice a year.
- f. Meters and scales- All scales and metering devices shall be tested for accuracy upon installation. Batch scales and micro-ingredient scales should be cleaned and inspected regularly. All scales shall be professionally serviced annually.
- g. Pelleting and pellet cooling, the following indicators of quality shall be examined regularly:
 - 1) Conditioning temperature
 - 2) Cool pellet temperature
 - 3) Moisture gain
 - 4) Pellet durability

3.9 Feed Ingredient Quality

- a. The manufacturer shall have an ingredient quality assurance program. The manufacturer shall maintain standard operating procedures for ingredient quality assurance.
- b. All feed ingredients shall be FDA approved. Feed ingredients not approved by the FDA will have to be approved by the NIH Contract Officer and the Laboratory Animal Nutritionist for use in laboratory animal feed.
- c. The manufacturer shall maintain ingredient quality assurance records, and shall provide these records to the Government Inspector at the time of inspection of the facility. The manufacturer shall have in writing specifications for each ingredient. The minimum ingredient specifications shall include, but not be limited to the following:
 - 1) visual appearance of the ingredient,
 - 2) physical characteristics of the ingredient (i.e. bulk density),
 - 3) sampling procedures,
 - 4) acceptable analytical assay values for nutrients and contaminants,
 - 5) analytical assay methodology.
- d. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current FDA regulations, guidelines, and action levels for poisonous or deleterious substances. Compliance with this requirement may be accomplished by purchasing ingredients under a supplier's guarantee or certification, or may be verified by analyzing the ingredients for aflatoxins and other natural toxins.
- e. There shall be a system in place that will prevent the use of out-dated ingredients, such as vitamins, minerals and premixes, in the production of laboratory animal feed. An out-

of-date ingredient is one that has been stored longer than the manufacturer's recommended shelf life.

- f. **Product Sample** - The feed manufacturing contractor shall be responsible for collecting a representative sample (approximately 2 kg) from each production batch of product manufactured for the NIH. For the purposes of this Specification, a "batch" shall be defined as one continuous production run which may or may not consist of several small batches. In those instances where more than one batch is required to make up a production run for one shipment, samples for testing shall be made up using an equal portion of each of the small batches and one (1) sample will be sufficient for that production run or shipment. The minimum number of feed bags sampled shall be calculated by using the square root of the total number of bags of feed per production batch. The samples shall be shipped within 24 hours after the manufacturing process is completed as designated at the time the feed contract is awarded. Each sample shall be identified as to the name of manufacturer, the name of the product, the NIH Stock Number, and the date of manufacture. No coding of these items will be allowed.

4. Transportation

- a. Railroad cars and trucks transporting laboratory animal feeds shall be as free as is practical of dirt, trash, and objects that could contaminate or puncture paper bags. The truck or railroad car shall be free of contamination by any chemical compound known to be undesirable.
- b. The vehicles shall be water tight and so constructed to prevent entrance of rodents, birds, or insects.
- c. Laboratory animal feeds shall be shipped on new unused pallets. The pallets shall be dry, clean, pest-free, and uncontaminated by undesirable chemicals.
- d. Laboratory animal feeds shall not be transported with products containing antibiotics or drugs, fertilizers, or any chemical compounds known to be undesirable.

4.1 Inspection

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 National Institutes of Health personnel. Failure to comply with the requirements of this standard shall constitute sufficient grounds for withholding contract award or for cancellation of existing contract(s).