



**INSPECTION REPORT**

APR 10 2007

835 cust\_id  
325034 insp\_id  
8451 site\_id

**SOUTHERN BIOTECHNOLOGY  
ASSOC., INC.**

Customer ID: 835

Certificate: 64-R-001E

Site: 001

P.O. BOX 26221  
BIRMINGHAM, AL 35260

SOUTHERN BIOTECHNOLOGY  
ASSOC.

Inspection  
Type: ROUTINE INSPECTION

Date: MAR-12-2007

- 2.31 ( a ) REPEAT NCI
- 2.31 ( d ) ( i ) ( ii ) REPEAT NCI
- 2.31 ( d ) ( i ) ( iii ) REPEAT NCI
- 2.31 ( e ) ( 2 ) REPEAT NCI

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures.

\*\*\*The IACUC committee is composed of five members. Discussion with two of the members and documentation/or lack of documentation reviewed today and in past inspections indicate that training in IACUC functions is necessary.

The following noncompliance's in IACUC function documented on previous inspections (08/22/06, 06/01/06 and 06/05/05) have not been corrected (i.e. the protocols do not provide the information that is required in Sections 2.31 (d) and (e), for example; written assurances that the research is not unnecessarily duplicative, a search for alternatives, and justification of numbers and rationale for species requested. Clarification of the Roles and responsibilities of the IACUC and IACUC function is necessary. I have discussed the need for further training with the IACUC Chairperson (recently replaced), the Institution Official and Facility Manager. I have provided information on formal training courses and seminars occurring locally and nationally and I have provided information on some of the websites that contain information for IACUC's that can assist them in meeting their training needs.

(d)(1) The IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

\*\*\*The antibody producing protocols use Complete Freund's adjuvant for the initial injection. The IACUC revised the protocols in September of 2006, but there is no documentation or written narrative indicating the facility has considered alternatives to this potentially painful procedure included in the protocol provided for review during this inspection. A written narrative describing the methods and sources used to determine no alternatives were available must be included on the protocol.

(d)(1)(iii) The IACUC shall determine that the following requirements are being met: principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.

\*\*\*The antibody production protocols do not contain a written assurance that the procedures are not unnecessarily duplicative.

Prepared By: Michelle B. Williams DVM  
MICHELLE WILLIAMS, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER . Inspector ID: 2028

Received By: \_\_\_\_\_

Title:

Date:  
MAR-14-2007

Date: 3/15/07



INSPECTION REPORT

835 cust\_id  
APR 10 2007 325034 insp\_id  
8451 site\_id

written assurance that the research is not unnecessarily duplicative must be included in the protocols.

(e)(2) A proposal to conduct an activity involving animals or to make a significant change in an ongoing activity involving animals must provide a rationale for involving animals and for the appropriateness of the species and numbers of animals to be used.

\*\*\*There is no rationale provided in the protocols for involving animals and for the appropriateness of the species and numbers of animals to be used. IACUC minutes indicate this noncompliance was discussed at the last IACUC meeting in September 2006 at which time the protocols were revised but no statement was added to the protocol. A statement containing the rationale for using animals, the appropriateness of the species and the numbers used must be provided in the protocol.

2.32 ( a )

PERSONNEL QUALIFICATIONS.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel as required in Section 2.32 (b).

\*\*\*Two of the three employees at the farm have recently been replaced. The Vivarium Manager has been employed for three months and has full responsibility at the farm. The animal caretaker has been employed at the facility for less than three months and is required to handle the animals. There is no documentation indicating these employees have been trained to perform their duties. Documentation of previous experience, training provided at the facility, and any previous training applicable to their position must be maintained and updated as necessary. It shall be made available for review during inspection. Correct by May 15, 2007

2.33 ( b ) ( 2 ) REPEAT NCI DIRECT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b)(2) Each research facility shall establish and maintain programs of adequate veterinary care that includes the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

\*\*\*The upper barn contains approximately 50 goats (groups 7 & 8). There were several goats in the upper barn with overgrown hooves. I observed three goats with overgrowth severe enough to cause the claws to deviate while walking which can result in injury and lameness. The hooves shall be trimmed routinely at a frequency that will provide adequate husbandry and protect the health of the animals.

3.57 REPEAT NCI

EMPLOYEES.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

\*\*\* A shortage of personnel has been documented previous inspections. There are currently three employees on the farm; one less than previous inspections. The grooming schedule for the rabbits has been delayed while the employees are performing other tasks. Insufficient husbandry practices can negatively affect the rabbit's health and well-being. The current number of employees is insufficient to maintain an adequate level of husbandry practices.

Prepared By: Michelle B. Williams DVM  
MICHELLE WILLIAMS, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector ID: 2028

Date:  
MAR-14-2007

Received By: \_\_\_\_\_

Date: 3/15/07

Title:



INSPECTION REPORT

APR 1 2007

835 cust\_id  
325034 insp\_id  
8451 site\_id

3.132 REPEAT NCI  
EMPLOYEES.

A sufficient number of adequately trained employees shall be utilized to maintain the professionally acceptable level of husbandry practices set forth in this subpart. Such practices shall be under a supervisor who has a background in animal care.

\*\*\* A shortage of personnel has been documented repeatedly on previous inspections. There are currently three employees on the farm, one less than previous inspections. The current number of employees is insufficient to adequately maintain the facility and the number of animals housed within. Several regular husbandry procedures are late or have not been carried out at a frequency that provides an acceptable level of husbandry. The following items are indications that additional employees are necessary:

1) Based on the schedule the hoof trimming for the goats began a month late. This rotation of hoof trimming has taken six days and there are two groups of goats yet to have their hooves trimmed. There are approximately fifty goats in these two groups and within that group I observed several (greater than 15) with hooves in need of trimming.

2) The rabbit grooming has been delayed while catching up on the goats.

3) There is much improvement in the records maintained on the farm; however, they are not yet complete. The inventory is missing information as to acquisition and the number of animals currently housed at the facility.

4) On today's inspection according to the records there are 288 goats, 83 rabbits, 17 donkeys, 4 pigs and 2 sheep. With one employee on leave there are only two employees remaining to clean, feed, update records and conduct the technical procedures scheduled for the day. The remaining hoof trimming and rabbit grooming will be delayed until the third employee returns.

Inadequate husbandry practices can lead to an increase in illness and disease. Proper husbandry must be provided to minimize disease hazard and to adequately maintain the animals. Based on these recurring noncompliances, additional employees are necessary to adequately maintain the facility.

Prepared By: Michelle B. Williams, DVM  
MICHELLE WILLIAMS, D V M , USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER , Inspector ID: 2028

Received By:

Title:

Date:  
MAR-14-2007

Date: 3/15/07