

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 82-R-0002  
CUSTOMER NUMBER: 1079

FORM APPROVED  
OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY**  
(TYPE OR PRINT)

Regents Of The Univ. Of Idaho  
University Of Idaho  
P.O. Box 443010  
Moscow, ID 83844

Telephone: (208) -885-8958

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS ( Sites ) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. ( An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs					- 0 -
5. Cats					- 0 -
6. Guinea Pigs					- 0 -
7. Hamsters					- 0 -
8. Rabbits				2	2
9. Non-human Primates					- 0 -
10. Sheep			31		31
11. Pigs					- 0 -
12. Other Farm Animals					
Goat			13		13
13. Other Animals					
Cattle			23		23

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
( Chief Executive Officer or Legally Responsible Institutional Official )

Signature

(b)(6),(b)(7)(c)

N

(b)(6),(b)(7)(c)

(Type or Print)

DATE SIGNED

24 Nov 2008

NOV 25 2008

### Column E Explanation

1. Registration Number: 82-R-0002
2. Number of animals used in this study: 2
3. Species (common name) of animals used in the study: Rabbit
4. Explain the procedure producing pain and/or distress.

Young adults of either sex are used for toxicity experiments. The minimum number of animals are used that will give interpretable results. Generally, this is two per toxin. If both of the two animals exhibit the same reaction, generally positive or negative, we do not test further. However, in some cases where the results are not conclusive, we may need to use additional animals, generally groups of three. In some toxicity tests, the toxins are injected IV, in others they are slowly released from subcutaneous (surgically-implanted) osmotic pumps.

Clinical effects of toxins used include fever, lethargy, and mortality, with mortality being the key indicator of toxin severity. Although not 100% accurate, previous study results have indicated loss of righting reflex is a good indicator of impending mortality and is thus used as the endpoint of the experiment.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)

Although the mechanisms involved in induction for staphylococcal food poisoning and toxic shock syndrome are currently not completely understood, it is known that the events leading to these diseases are multifactorial and complex. Thus, no tissue culture or cell technique that represents the ability of the toxins to cause either of these human diseases is known. It is our long-term goal to promote both human and animal well-being through this research. To achieve this goal, it is essential that we obtain an in depth knowledge of the structural and functional organization of these bacterial toxins. The morbidity and mortality associated with toxigenic staphylococcal and streptococcal diseases is significant for both humans and other animals. For example, toxic shock syndrome and the newly described "flesh eating" streptococcal disease fall into this category. Furthermore, diseases of domestic farm animals such as mastitis are highly associated enterotoxin-producing staphylococci. It is likely that the toxins modify the immune response in animals, as in humans, allowing the organism to persist and cause infection. This research will help us identify the regions of toxin molecules and then to test potential vaccine candidates possessing these regions in animals to determine if they induce protection.

Antibodies are used to purify toxins from staphylococcal cultures and also check for structural changes caused by any mutation that we introduce in the protein molecules. Rabbits are used for toxicity testing. They are the best model for human toxic shock syndrome, another illness caused by the toxins studied in this project. It is hoped that these studies will provide some insight into the molecular and cellular mechanisms of action of this group of toxins and lead to the development of systems that allow us to continue similar studies without animals.

The only effective means of preventing distress associated with the toxicological process would be to suppress the shock response, inhibiting the ability to determine if the toxin is clinically active and thereby negating the purpose of the experiment. Therefore, animals are not administered analgesics, tranquilizers, or other medical therapies to combat toxin effects. Instead, when loss of righting reflex occurs animals are euthanized.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102)

Agency: \_\_\_\_\_ CFR: \_\_\_\_\_

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