

MARINE MAMMAL COMMISSION
4340 EAST-WEST HIGHWAY, ROOM 905
BETHESDA, MD 20814

17 January 2007

William T. Hogarth, Ph.D.
Assistant Administrator for Fisheries
National Marine Fisheries Service
1315 East-West Highway, Room 14564
Silver Spring, Maryland 20910

Dear Dr. Hogarth:

In letters commenting on marine mammal permit applications submitted by the National Marine Mammal Laboratory and other National Marine Fisheries Service research facilities, the Marine Mammal Commission has repeatedly expressed concern about the failure of these facilities to establish Institutional Animal Care and Use Committees (IACUCs) as required under the Animal Welfare Act. These instances included applications for studies on Steller sea lions that were enjoined last year by a federal court and will soon be coming up for reconsideration on an expedited basis. As such, this is an opportune time to resolve the issue of IACUCs before it resurfaces in the context of specific applications. Doing so now should give the Service sufficient lead time to come into compliance with the Animal Welfare Act before these new permit applications are reviewed by the Commission and the public.

Both the Marine Mammal Commission and the Animal and Plant Health Inspection Service (APHIS), the agency responsible for implementing the Animal Welfare Act, have advised the Service that the applicable regulations require it to establish and use IACUCs for its facilities that use live animals for research or experimentation. This includes not only research in captive settings but also field studies involving invasive procedures or those that harm or materially alter the behavior of the animals being studied. The attached letter from the senior veterinarian responsible for marine mammal programs in APHIS's Animal Care office explains the legal requirements and the applicability of the regulations concerning IACUCs to the Service's research activities.

The Commission understands why there might be some confusion with respect to the requirement that federal research facilities that conduct research on marine mammals in the wild establish and use IACUCs. Most of the substantive requirements and detail concerning the establishment, functions, and use of these committees are set forth in section 2.31 of the applicable APHIS regulations (9 C.F.R. § 2.31). Section 2.31(d)(1) specifies that "field studies as defined in part 1" of the regulations are exempt from the requirement that an IACUC review research activities involving animals covered by the regulations. The term "field study" is defined in section 1.1 of the regulations as "any study conducted on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study." Thus, although some of the Service's research conducted in the field may be exempt, many activities are not. For them, the Service is required to establish IACUCs and adhere to the applicable Animal Welfare Act regulations. With respect to the question of whether federal facilities are subject to these same requirements, section 2.37 of the regulations specifies that

IACUCs for federal research facilities shall have the same composition, duties, and responsibilities as those required of non-federal research facilities under section 2.31 of the regulations, except for some minor differences concerning oversight responsibilities. For these reasons, we believe that it is clear that many of the field studies conducted by the National Marine Fisheries Service are subject to the IACUC requirements.

As explained in the attached letter from APHIS, review and approval of proposed research activities by an IACUC are required if the research will involve sedating, tranquilizing, immobilizing, or anesthetizing marine mammals. As indicated in the letter, review and approval by an IACUC also are required for studies that can be expected to alter, more than momentarily, the behavior of the animals. Branding animals, implanting tags, and capturing and retaining animals for longer than it takes to measure them are identified specifically by APHIS as activities that would trigger IACUC review. In the Commission's view, this list should be expanded to include any proposed studies that involve "intrusive research" procedures as defined by the Service in its Marine Mammal Protection Act regulations (50 C.F.R. § 216.3). Several routine research activities, such as attaching tags, taking biopsy, blood, or milk samples, collecting swab samples, or tooth extraction, would fit within this definition. Moreover, as explained in the letter from APHIS, decisions concerning what activities fit within the field study exception should not be made by the researcher alone but should be confirmed by the IACUC.

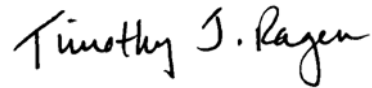
The issue of IACUCs came up during a 24 May 2006 meeting of National Marine Fisheries Service and Commission representatives at which a number of permit-related issues were discussed. The Commission reiterated its position that such committees were mandatory for much of the field research conducted by the Service, and the Commission advised the Service that it either should establish IACUCs without delay or provide valid arguments to support a decision not to do so. Some Service participants remained skeptical as to whether the IACUC requirements applied to their research activities and indicated that they intended to seek clarification from APHIS on this point. We have heard nothing since then to indicate that the Service has completed, or even initiated, consultation with APHIS. Our reading of the applicable laws and regulations, and the APHIS interpretation of them, is that unless the Service restricts its research to activities that are non-invasive and cause no harm or disturbance, the involved facilities are required to establish IACUCs.

This is a relatively simple matter of statutory and regulatory construction that should be subject to quick resolution through consultation with NOAA's General Counsel's Office or with APHIS or Department of Agriculture officials. The Marine Mammal Commission therefore recommends that the National Marine Fisheries Service take immediate steps to resolve this issue and either (1) take the necessary steps to establish IACUCs or (2) provide the Commission with a detailed explanation as to why these requirements do not apply to the marine mammal research being conducted by the Service. The Commission further recommends that the Service's permit office refrain from issuing permits for research that is invasive or may harm or substantially disturb marine mammals to applicants that have not satisfied the requirements of the Animal Welfare Act, including review and approval of such activities by an IACUC.

William T. Hogarth, Ph.D.
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Please contact me if you have any questions concerning these recommendations or the other points raised in this letter.

Sincerely,



Timothy J. Ragen, Ph.D.
Executive Director

Attachment

cc with attachment: Mr. Frank P. Almeida, Northeast Fisheries Science Center
John L. Bengtson, Ph.D., National Marine Mammal Laboratory
Mr. Alex Chester, Southeast Fisheries Science Center
Douglas P. DeMaster, Ph.D., Alaska Fisheries Science Center
William W. Fox, Jr., Ph.D., Southwest Fisheries Science Center
Karl Gleaves, Esq., General Counsel for Fisheries
Barbara A. Kohn, D.V.M., Animal and Plant Health Inspection Service
Mr. P. Michael Payne, Chief, Permits Division
Samuel G. Pooley, Ph.D., Pacific Islands Fisheries Science Center
Nancy B. Thompson, Ph.D., Northeast Fisheries Science Center
Usha S. Varanasi, Ph.D., Northwest Fisheries Science Center