



Public Employees for Environmental Responsibility

962 Wayne Avenue, Suite 610 • Silver Spring, MD 20910

Phone: (202) 265-PEER • **Fax:** (202) 265-4192

Email: info@peer.org • **Web:** <http://www.peer.org>

Complaint Summary: Loss of Scientific Integrity

The principal wildlife disease laboratory for the U.S. Geological Survey (USGS), the National Wildlife Health Center in Madison, Wisconsin, has suffered from a number of serious deficiencies and deviations from accepted scientific standards.

Due to an exemption in the Animal Welfare Act, this facility is not subject to external oversight. Unfortunately, USGS has used its self-regulating status as an excuse to ignore or minimize deficiencies found in recent years. As a result of these significant and sustained departures from accepted professional practices, the reliability and value of the important scientific work at this critical lab have been compromised.

Through this complaint, Public Employees for Environmental Responsibility (PEER) seeks to remedy this demonstrated loss of scientific integrity by urging that the USGS take the following steps: 1) directly correct these documented deficiencies; and 2) accede to international research accreditation for all of its research centers in order to prevent recurrence of these serious lapses.

Complaint

I. Authority

PEER is filing this complaint pursuant to the Departmental Management Manual provisions for the U.S. Department of Interior (DOI) governing “Integrity of Scientific and Scholarly Activities” (305 DM 3). In relevant part, this DOI policy stipulates that:

“The Department will not tolerate loss of integrity in the performance of scientific activities or in the use of scientific products in decision making.” (§ 3.4B)

It defines scientific integrity as “The condition that occurs when persons covered by this chapter adhere to accepted standards, professional values, and practices of the relevant scientific community...” (§ 3.5A) The policy sets an exacting standard that “Scientific information considered in Departmental decision-making must be robust, of the highest quality, and the result of as rigorous a set of scientific processes as can be achieved...” (§ 3.4)

The heart of this complaint revolves around the loss of scientific integrity as defined by the DOI policy:

“Loss of Scientific Integrity. Occurs when there is a *significant departure from the accepted standards, professional values, and practices of the relevant scientific community*... Loss of scientific integrity negatively affects the quality or reliability of scientific information.” (§ 3.5 B) [Emphasis added]

II. Applicable Scientific Standards

Appropriate Animal Care and Use (ACUC) of research animals is integral to the scientific validity of results from experimental studies. Just as scientific instruments must be calibrated to ensure scientific integrity, research animals must be effectively “calibrated” by ensuring adequate housing, nutrition, husbandry, and veterinary care. Without an adequate baseline for these potentially compounding variables, researchers cannot obtain high quality repeatable results. In short, when an animal exhibits poor health or dies, researchers must know whether this was due to a pre-existing condition, the experimental treatment, or to other unrelated factors such as lapses in animal care. Without conducting ante- and post-mortem examinations on all animals, this cannot be determined.

There are established standards for animal care which, when applied uniformly throughout the research community, facilitate confident comparison of findings from similar species and procedures. The standards specify the role that good housing, nutrition, husbandry, and veterinary care play in maintaining healthy animals used in research.

For example, the National Academies of Science Guide for the Care and Use of Laboratory Animals (“NAS Guide”) was created to: “... uphold the scientific rigor and integrity of biomedical research with laboratory animals as expected by their colleagues and society at large.” The NAS Guide governs the use of animals in all research that receives Public Health Services funding, as well as other federal funding sources.

In addition, the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (1985), which states, “The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable Federal laws, guidelines, and policies.”

Similarly, the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (last rev. 2015) incorporates U.S. Government Principles cited above and explains how to meet PHS Assurance standards. PHS requires that each research facility performing animal research with PHS funds file an Animal Welfare Assurance describing how the facility will comply with PHS Policy. The National Institutes of Health (NIH) Office of Laboratory Animal Welfare (OLAW) manages the Assurance program. OLAW does not itself conduct inspections to ensure compliance, but it requires semi-annual facility inspections and procedural reviews by an Institutional Animal Care and Use Committee (IACUC).

These are the standards that the USGS violated and, we believe the record shows, continues to violate, in operating its National Wildlife Health Center (NWHC).

III. Loss of Scientific Integrity

Documents obtained by PEER through litigation against the USGS under the federal Freedom of Information Act (FOIA) indicate that the USGS was non-compliant with accepted scientific standards in its operation of the NWHC.

The July, 2013 semi-annual inspection report from the IACUC to the NWHC Center Director listed at least 23 significant programmatic and facility deficiencies (defined as: those that are, or may be, a threat to animal health or safety). After receiving notification about the July, 2013 inspection report, the NIH Office of Laboratory Animal Welfare Director, Division of Compliance Oversight, determined that OLAW "...has serious concerns about the ability of the NWHC to maintain an ongoing program of animal care and use that is compliant with the provisions of the PHS Policy and the Guide..."

An independent consultant review in August, 2013 recognized the deficiencies caused by lack of staffing and funding and stated that the NWHC ACUC program was "on the edge of possible failure."

In addition, there have been at least eight specific animal care related violations reported to OLAW from 2010-2014:

1. Deaths of 16 mallard ducklings in shipping (2010)
2. Death of Mexican free-tailed bat due to poor caging (2012)
3. Inadequate training of individuals working with research animals (2013)
4. Live vole discarded with bedding (2013)
5. Death of *Peromyscus* mouse (2013)
6. Death of 14 voles (2013)
7. Non-compliance with PHS policy (2013)
8. Death of four zebra finches. (2014)

Facility reviews also indicate a number of quality assurance violations and related staffing deficiencies, such as Attending Veterinarians¹ who have often been active animal researchers (thus compromising independent oversight), and/or inexperienced veterinarians. A veterinarian with prior facility experience was temporarily re-assigned to serving as the Attending Veterinarian in April, 2013; this individual was a non-research veterinarian.

Having coverage provided by a veterinarian inexperienced with animal research is considered a poor practice, as stated in one inspection report:

¹ Attending Veterinarians are those with program responsibility; other veterinarians may additionally be providing clinical care to the animals subject to experimentation.

“Clinical care and implementation of many of the veterinary policies mandated by the Guide has been the responsibility of a list of veterinarians hired as Research Work Order contractors, temporary employees, permanent employees serving a collateral duty, part-time employees or reassigned individuals.”

Moreover, the NWHC had made false claims that back-up veterinary care would be provided by a veterinarian from the University of Wisconsin-Madison School of Veterinary Medicine, as no such arrangement was ever effectuated.

In short, the records detail systematic departures from accepted scientific standards in the operation of this facility.

IV. Failure to Correct Lapses in Scientific Integrity

Nor do the records obtained in the FOIA lawsuit indicate that USGS NWHC has taken complete and meaningful corrective steps. The records show that from the December 2013 through July 2015 inspections, some of the same deficiencies continue to be reported without resolution. Additionally, the NWHC’s record-keeping has been a significant departure from the accepted standards, professional values, and practices of the relevant scientific community, particularly with respect to necropsy records and procedures.

An internal review that the USGS Midwest Region office conducted of the NWHC ACUC program, acknowledged that there was room for improvement and the need for additional training, then proceeded to minimize the magnitude of the deficiencies reported.

The records produced from the FOIA lawsuit further document that serious problems continued and are still ongoing. For example:

- Only a small percentage of animals that died or were euthanized were submitted for necropsy to identify a cause of death from August, 2013 to present. These analyses are critical to monitoring the health of animal populations and to validating scientific conclusions drawn from the animal deaths;
- The medical records system has not been adequate to provide thorough and consistent monitoring to determine trends in animal health. A new electronic system to replace paper records was still not functional as of summer 2015; and
- In January 2015, a significant deficiency was reported that was serious enough to warrant removing all animals from the facility and closing it down.
- As far as we can tell, USGS still lacks any specific written guidance for its research centers to assure compliance with the AWA and applicable scientific standards.

In short, the NWHC’s reliance on internal IACUC reviews has been sorely ineffective in managing the animal care and use program to meet required standards.

V. Significance of Lapses

On its website, the USGS bills itself as “the Nation’s premier earth and biological science agency.” The NWHC, the principle USGS wildlife disease laboratory, states its mission is “...to provide national leadership to safeguard wildlife and ecosystem health through dynamic partnerships and exceptional science.” Yet as detailed above it suffers from a number of preventable deviations from accepted scientific standards.

Moreover, the work of the NWHC is a key contributor to DOI and other federal agency decision-makers addressing management steps on significant diseases of wildlife, domestic animals, and humans. These diseases include serious maladies affecting both wildlife populations and human health, such as:

1. Sylvatic Plague
2. White Nose Syndrome in Bats
3. Chronic Wasting Disease
4. Newcastle Disease Virus
5. Avian Influenza
6. West Nile Virus
7. Monkeypox

Because it cannot be assured that these animals in NWHC research were in optimal health prior to, and during these studies, the scientific validity of findings from studies involving these animals may be suspect.

Requested Remedy

Most animal research facilities have external oversight through reporting to, and routine inspections by, the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS). However, under the terms of the Animal Welfare Act, *federal* animal research facilities are not inspected by – nor must they report to – USDA.²

Nonetheless, many Federal agencies ensure the scientific integrity of their research by arranging for inspection and accreditation by an unaffiliated external organization such as the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), which provides an alternative to USDA inspections. Federal agencies which voluntarily subject their laboratories to this independent accreditation include:

- i. The Centers for Disease Control (Atlanta and Ft. Collins);
- ii. Department of Defense (ex. Uniformed Services University of the Health Sciences);
- iii. Department of Energy (Lawrence Livermore and Oak Ridge);

² They do have to report numbers of mammals used (other than mice and rats), as well as the number subjected to pain or distress.

- iv. Environmental Protection Agency research centers and laboratories;
- v. Food and Drug Administration research centers;
- vi. National Aeronautics and Space Administration (Ames, Kennedy, Johnson Centers);
- vii. National Institute of Health, Institutes and Intramural Programs;
- viii. USDA research centers; and
- ix. Veterans Affairs Medical Centers, Hospitals, and Health Care Systems.

If these agencies acceded to independent accreditation of their laboratory facilities, the lack of such accreditation at USGS – Interior’s premier science agency – is a glaring deviation.

Thus, to cure the inadequate internal review and the lack of external oversight for the Animal Care and Use Program at the NWHC (and all of the other USGS Research Centers), the USGS should move to acquire AAALAC International accreditation for all its centers that use animals in research.

The prospect of external oversight by an accrediting organization would be a potent incentive to bring programs into compliance. Such an action would also promote public confidence in the future quality of USGS animal research, as required by the DOI Scientific Integrity Policy when it prescribes that all of the scientific information the agency relies upon “must be trustworthy.” (§ 3.4)

Respectfully submitted on January 12, 2017 by
Public Employees for Environmental Responsibility