PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY
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May 5, 2022

The Honorable Mark Lee Greenblatt
Inspector General
U.S. Department of the Interior
1849 C Street, NW Mail Stop 4428
Washington, DC 20240

RE: Request for Investigation

Dear General Greenblatt:

The United Sates remains in the grip of a pandemic caused by the transmission of COVID-19, a zoonotic disease. The events of the past two years should provide a cautionary tale about the great care that should be taken by government laboratories to prevent releases of pathogens causing animal-to-human transmissible diseases.

Unfortunately, U.S. Geological Survey (USGS) wildlife disease labs suffer from dangerous breaches in biosecurity causing environmental releases of dangerous pathogens, according to reports from current and former USGS scientists and agency records obtained under the Freedom of Information Act (FOIA), including an ongoing FOIA lawsuit. In addition, USGS has avoided reporting these breaches to relevant state and federal regulatory agencies. Further, USGS has taken steps to prevent their scientists from monitoring lab conditions and/or reporting breakdowns both internally and externally.

The agency has also pursued retaliatory actions against one microbiologist who was legally required to report these breakdowns to federal and state authorities, and who filed a Scientific Integrity complaint over gross deviations from lab protocols that compromised biosafety standards, animal welfare conditions, and experimental results.

To address this sobering state of affairs, I am writing on behalf of Public Employees for Environmental Responsibility (PEER) to ask that the Office of Inspector General (OIG) of the Department of Interior conduct a vulnerability review of the USGS wildlife disease laboratories and identify potential steps, including independent accreditation of these USGS facilities, to prevent or minimize the needless release of viruses and other pathogens and avoid animal care deficiencies, due to equipment malfunctions and negligent maintenance practices.

Introduction

Zoonotic diseases such as coronaviruses are caused by germs that spread between animals and people. Thus, researching animal diseases requires high levels of biocontainment to prevent releases of viruses and other pathogens to prevent spread both to humans and other animals.

The USGS maintains biosafety level (BSL)-2 and BSL-3 laboratory facilities at three locations in the U.S.: The Western Fisheries Research Center (WFRC) in Seattle, Washington; the National Wildlife Health Center (NWHC) in Madison, Wisconsin; and the Eastern Ecology Science Center laboratories (EESC), formed last year through the merger between the Patuxent Wildlife Research Center in Maryland, S.O. Conte Research Laboratory in Massachusetts, and the Leetown Science Center in West Virginia. These facilities handle potentially deadly infectious diseases.

In recent years, USGS biosafety labs have suffered from crippling maintenance problems due to frequent equipment failures and lack of independent oversight. These breakdowns at high-level federal biosecurity labs have spread pathogens and endangered staff safety, while compromising animal welfare and the validity of experimental results.

I. Lab Conditions

In a 2021 letter, the American Veterinary Medical Association and other groups called for additional funding for the NWHC, a BSL-3 laboratory, as the "current facilities are 40-50 years old...." In October 2020, USGS Director Jim Riley suspended NWHC work using coronaviruses because of concerns over facility safety issues.

Beyond coronaviruses, the NWHC works with diseases including Sylvatic Plague, Chronic Wasting Disease, Newcastle Disease Virus, Avian Influenza, West Nile Virus, and Monkeypox. As detailed below, it has suffered a number of equipment malfunctions and contaminated wastewater releases in recent years.

At the same time, the WFRC facility in Seattle has also suffered numerous effluent breaches from both its BSL-2 and BSL-3 labs, the latter of which is closed due to breakdowns in its wastewater treatment and ventilation systems.

Both facilities, NWHC and WFRC, have experienced multiple biocontainment breaches resulting in releases of untreated pathogen-contaminated wastewater into the environment that the Centers' leadership tried to cover up even from the USGS executives in its Reston Headquarters. While some of these biosafety failures and deaths of research animals have been reported, the full extent of the repeated incidents, danger to the public/environment, and negligence by USGS research center leadership has not been fully publicly disclosed.

a. Environmental Releases

Western Fisheries Research Center (WFRC)

The WFRC operates two types of aquatic animal containment/quarantine biosafety laboratories (lab); biosafety level-2 (BSL-2) and biosafety level-3 (BSL-3). This facility conducts scientific research involving dangerous endemic and exotic aquatic pathogens.

A series of biocontainment and maintenance breakdowns at WFRC resulted in it discharging aquatic viruses into freshwaters in Washington State for a six-month period during 2017.

On June 29, 2017, WFRC officials discovered that its BSL-2 lab had been discharging untreated or partially treated pathogen-contaminated wastewater into the wetland in Warren G. Magnuson Park draining into Lake Washington, the state's second largest lake. The lab's effluent treatment system was last checked the prior January. The BSL-2 lab's chlorination system had broken down, but it lacked (and still lacks) an alarm to indicate when its chlorine line is clogged. On July 21, 2017, the USGS acknowledged this containment failure in a "Notice of Standard Operating Procedure Deviation." However, WFRC administrators did not know for how long, and how many, pathogens were flushed into Lake Washington, which also is the source of the lab's water.

While the pathogens WFRC uses in animal testing are not known to cause human disease, the BSL-2 lab tests aquatic pathogens from the entire Pacific Northwest region, some of which are foreign to Lake Washington. Furthermore, the experimental animals carry their own unknown microflora that could be harmful to the wetland and ecosystems of Lake Washington.

Documents obtained by PEER from public record requests indicate that this incident did not prompt WFRC to install a chlorine meter alarm or real-time wastewater treatment monitoring system. Instead, WFRC administrators merely proposed to tighten monitoring protocols. These records also reflect that no other corrective action was imposed or taken at that time.

In the intervening months, records obtained by PEER indicate that there have been several other breaches, including –

- A series of BSL-2 effluent treatment failures from January through March 2018, but they were not reported until September 2018. These involved at least three more wastewater system incidents of improperly treated wastewater (e.g., post-treatment testing of chlorine levels were below set standards);
- The BSL-3 laboratory shut down in March 2018 after two effluent containment breaches/leaks and air quality issues in the main lab occurred. The first BSL-3 untreated wastewater leak likely started in Nov 2017;
- In March 2018, a second leak was found occurring from underneath a BSL-3 treatment tank. Apparently, this was thought to be from an ongoing earlier leak from the contaminated effluent transfer pipe that was also not initially reported;
- On April 1, 2021, a contractor filling the salt bin in the BSL-2 Electrochlorination System caused an air blockage in the chlorine generation equipment. Four days later (April 5), it was discovered that there were insufficient chlorine levels to properly decontaminate the BSL-2 effluent. The untreated wastewater was estimated to have been released for two - three days. This wastewater contained a fish pathogen (infectious hematopoietic necrosis virus) from an ongoing experiment. The post-incident recommendation was to now begin monitoring post-treatment chlorine levels on the weekends, not just weekdays;

- Over the past three years, there have been intermittent reports of low to zero post-treatment chorine levels on "heavy rain days" in Seattle (first formally reported in November 2018). WFRC assumes that treatment of BSL-2 lab wastewater is still adequate, because the rainwater is only diluting the post-treatment effluent sample taken at an outdoor pipe outlet. As a result, WFRC currently still lacks any continuous automated method to consistently confirm that the wastewater is properly decontaminated; and
- The ultralow freezer, needed for storage of specimens and samples that follows the high-risk containment measures put in place when working with high-risk aquatic pathogens, has been removed from the BSL-3 lab and placed in a location not accessible to all staff.

We do not believe that the above recitation is a complete inventory of problems plaguing the WFRC labs. In addition, there is an approximately one-year lag in PEER's ability to obtain records from WFRC.

National Wildlife Health Center (NWHC)

Documents obtained by PEER through a lawsuit brought under the Freedom of Information Act in 2018 indicate that the NWHC suffers from what are labeled "significant programmatic and facility deficiencies" causing one consultant to describe the program as "on the edge of possible failure."

The July 2013 semi-annual inspection report from the Institutional Animal Care and Use Committee (IACUC) to the NWHC Center Director listed 23 significant programmatic and facility deficiencies (defined as: those that are, or may be, a threat to animal health or safety). In response to the July 2013 inspection report, the National Institutes of Health (NIH) Office of Laboratory Animal Welfare Director, Division of Compliance Oversight stated that it "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…"

In the subsequent eight years, these deficiencies have not been addressed and in some cases worsened, according to our review of records and discussion with NWHC.

Following this report –

- The NWHC BSL-3 Lab building's main sewer line pipe broke and untreated effluent leaked into the ground underneath the research center's building foundation, which constitutes as a contaminated wastewater release/spill into the environment. The pipe break is upstream of the NWHC on-site wastewater treatment system. This was first detected in November 2014, however the date when the pipe initially broke is unknown. On December 15, 2014, NWHC notified the CDC Select Agent Program of a "drain issue" from the BSL-3 labs. On April 8, 2015, NWHC follows up with the CDC disclosing that the drainage issue is more substantial and that it is "probably a break or hole" in the main effluent drainage pipe of the waste treatment system.
- Only after the contractor "confirmed sedimentary intrusion, a 30' sag along a 150' section of 4" main, and a fractured drain coupler" in the wastewater drainage system, did the NWHC then start a "phased" shutdown of research/experiments using pathogens and

transferring animals out 29 BSL-3 labs/rooms within the Animal Isolation Wing". However, many experiments continued, and some new ones started, based on the justification that they were not allowing a lot of fluid down the drain or running the experiments "dry".

- In May 2015, the contractor discovered that a comminutor (sewage grinder) was backed up and has not been "running for 20 years". (Comminutors break down wastewater solids in plant headworks and pump stations; it is heavily used because it is a critical part of the wastewater treatment process). That same month, the contractor also reported that drains in various BSL-3 labs are "severely deteriorated".

Beginning in April 2018, repairs were made to the NWHC effluent pipe/drainage system. In November 2020, PEER submitted a FOIA for information about the progress of these repairs, as well as for records concerning animal laboratory wastewater/effluent system malfunctions or deficiencies, including blocked/backed-up laboratory drains, insufficient inactivation of pathogens, biowaste treatment alarm failures, sewer drainpipe cracks and subsequent underground leaks and closure of the laboratory sections. The NWHC was unable to provide a timetable for production of any responsive documents. On February 20, 2021, PEER filed its second FOIA suit for NWHC records.

Those records are now being released but many what appear to be critically informative documents are heavily redacted or being withheld by USGS potentially necessitating months more litigation to obtain these records.

b. Compromise of Animal Welfare and Scientific Integrity

Scientific research protocols reviewed by Institutional Animal Care and Use Committees (IACUC) and Institutional Biosafety Committees (IBC) ensure the humane use of animals in experiments and the maintenance of biosafety contaminant standards, respectively, when conducting high risk 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 appropriate monitoring of equipment that supports animal well-being and maintains experimental conditions, the research outcomes and data can be compromised.

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), 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 and fail to report or downplay. At WFRC, for example, there have been numerous animal care incidents associated with maintenance personnel not monitoring/informing scientists of alarms concerning equipment malfunctions and ongoing poor water quality and temperature issues that impact animals and experiments.

The records produced from the 2018 FOIA lawsuit uncovered NWHC records showing that there have been at least eight specific animal care related violations reported from 2010-2014 and that –

- 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 July 2018. 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; 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.

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.

In early 2017, an investigation by the new USGS Ecosystems Mission Area biosafety specialist concluded that the NWHC Center Director should not be the institutional official for IACUC and that NWHC animal care staff did not have any experience in how to implement a proper IACUC program.
As far as we can tell, the USGS still lacks any specific written guidance for its research centers to assure compliance with the Animal Welfare Act and applicable scientific and biosafety standards.

II. Breakdown of Checks and Balances

a. Scientists Muzzled

Employees at these facilities who are aware of the issues/incidents are fearful to report the conditions especially because those staff members who have stepped forward have been punished. For example, a NWHC veterinarian who tried to report incidents and improve animal care was forced to retire.

A 28-year career research microbiologist, who supervised the aquatic WFRC BSL-3 laboratory disclosed both internally and to federal and state control agencies wastewater treatment and animal welfare problems in the BSL-2/3 laboratories. This scientist was placed on administrative leave for more than one year. She was terminated and, shortly thereafter, her termination was rescinded. Upon her return, she found that she was no longer allowed to manage the BSL-3 lab, a duty she performed for over the last 10 years, informed she could not freely access BSL-2 lab areas she previously conducted research in, could not rejoin the biosafety or animal committees, and other restrictions/exclusions were imposed.

This scientist's research has been blocked/delayed from being resumed and published, likely because some of her experimental studies demonstrate for the first time that aquatic rhabdoviruses are now also making novel host species jumps. In addition, her research findings indicated the same virus strains released during laboratory containment failures were potentially lethal not only to fish but could also kill native amphibian species residing in the wetland, where the contaminated wastewater was dumped.

Further, WFRC leadership have instituted policies to 1) prevent scientists from monitoring equipment maintenance issues by denying them access to key parts of the labs; and 2) remove authorization for staff to report any major incidents to outside regulatory agencies.

Facility reviews of NWHC also indicate several quality assurance violations and related staffing deficiencies, such as Attending Veterinarians who have often been active animal researchers (thus compromising independent oversight), and/or inexperienced veterinarians. 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, but no such arrangement was ever effectuated.

In short, USGS actively discourages its scientists from monitoring conditions and reporting biosafety problems. Secrecy surrounding biocontainment breaches makes repetition of these dangerous incidents in the future more, not less, likely.

b. Breaches Not Reported

In March 2015 following the release of untreated wastewater, the NWHC Director decided that the Center would not report this “accidental discharge of prohibited wastewater” to the City of

Madison Public Sewage District as it was required to do. Based on the documents released thus far it appears to have never been reported.

It appears that an NWHC employee may have leaked the information because the City of Madison Sewage District made an unexpected inquiry in April 2015 asking the NWHC to complete the District Industrial Request Discharge Form that was sent previously to the NWHC but there is no record indicating that it was ever returned.

Moreover, the NWHC does not know if the pathogens it released down the drains were inactivated or remained viable. The NWHC claims that the various disinfectant cleaners intermittently used in the BSL-3 labs likely rendered the pathogens non-viable and thus no environmental risk or public harm occurred. Nor did the NWHC test any soil or water samples. Thus, it remains unknown how far these potentially released pathogens and chemicals spread underground or if the wastewater connected into underground or surface water flows, and eventually into public water wells.

At WFRC, records are unable to confirm if this Center's releases of improperly treated wastewater were ever formally reported to the Washington Department of Ecology.

c. Current Outside Review Limited

In response to criticisms about these matters, USGS proclaims that its wildlife disease labs are regularly inspected by federal regulatory agencies, such as USDA's Animal and Plant Health Inspection Service (APHIS).

In fact, highly redacted FOIA responses from CDC and USDA APHIS show minimal inspections of USGS labs in the past two years. Three FOIA requests seeking corroborating inspection records from USGS itself have gone unanswered, compelling current litigation.

d. USGS Lab Quality Control at Issue

Events at other USGS labs also raise questions about the extent of management's quality control. For example, last year, the Nuclear Regulatory Commission investigated and fined USGS Research and Test Reactor facility located near Denver, Colorado for violations involving the lack of scientific integrity and data manipulation.

In 2022 it was reported that an analyst at the USGS National Water Quality Laboratory in Lakewood, Colo., revealed widespread falsification of control test results from March 2019 through June 2020. Beyond this analyst, other employees told investigators that broader problems existed at the lab, such as inadequate supervision and insufficient support, according to news reports.

III. Absence of Independent Accreditation

The accepted standards in the scientific community for live animal research laboratories include independent verification of providing animal test subjects with excellent care while minimizing their suffering and adhering to biosafety standards. In fact, numerous federal agencies have

voluntarily ensured the integrity of their programs by arranging for inspection and outside accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and/or the American Biological Safety Association (ABSA). These include:

1. The Centers for Disease Control (Atlanta and Ft. Collins)
2. Department of Defense (Uniformed Services University of the Health Sciences)
3. Department of Energy (Lawrence Livermore and Oak Ridge)
4. Department of Agriculture
5. Environmental Protection Agency
6. Food and Drug Administration
7. National Aeronautics and Space Administration (Ames, Kennedy, Johnson Centers)
8. National Institute of Health
9. Veterans Affairs

In contrast with the practice of all other federal agencies that handle animals, the USGS – self-proclaimed as the nation's premiere wildlife health science practitioner – is not independently accredited. Unlike other federal agencies listed above, the USGS has not voluntarily subjected their labs to external accreditation.

Independent accreditation would likely reduce the risk of future accidental releases of zoonotic and non-native pathogens from USGS wildlife research labs. Accreditation would also serve to improve the overall integrity and reliability of scientific information produced by those labs. In addition, outside accreditation would give USGS scientists an avenue to report concerns that would not be stifled.

Notably, a 2017 report to the USGS Director from the bureau's Biosecurity and Biosafety Specialist, indicated the NWHC "personnel is very enthusiastic about getting an AAALAC international certification". Yet, that idea then was rejected by USGS leadership; a rejection that was repeated after six leading wildlife conservation and humane NGOs urged the acting Director, by a letter dated March 18, 2021, to accept AAALAC or ABSA accreditation.

Without the autonomous oversight of accreditation, the USGS will continue to be able to subordinate bringing its animal research laboratory programs up to accepted standards to other budgetary or bureaucratic concerns. Biosecurity in working with dangerous wildlife diseases should not merely be a collateral consideration – it should be a nonnegotiable requirement.

Conclusion

As indicated above, PEER has obtained extensive documentation in support of these concerns. In addition, there are current and former employees with whom we are working with who can provide testimonial support on these shortfalls, and their consequences.

In 2013, in response to similar employee complaints channeled through PEER, the OIG declined to directly investigate and instead asked USGS to investigate the allegations. The USGS retained

a consultant to conduct a review which concluded that deficiencies were caused by lack of staffing and funding.

In the intervening years, the deficiencies at these labs have only worsened. It is also clear that these breakdowns transcend budgetary concerns. Further, allowing USGS to use the excuse of budgetary concerns enabled subsequent dangerous environmental releases of pathogens to occur.

In 2022, PEER urges the OIG not to make the mistake it made in 2013. Do not refer this back to USGS to investigate itself.

If the OIG lacks the expertise to undertake the vulnerability assessment that we urge, PEER recommends that you reach out to sister Inspector General offices that possess the requisite expertise.

Now that the OIG is on notice about these environmental and public health risks emanating from Interior Department facilities, we urge you not to walk away from this necessary task. It would be unconscionable if America or the world had to repeat the horrors of a major infectious disease outbreak due to the negligence of federal officials.

Sincerely,

Timothy Whitehouse
Executive Director