



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-2803

April 30, 2008

Re: Animal Welfare Assurance
A3368-01 [OLAW Case 1M]

Dr. William S. Mellon
Associate Dean for Research Policy
University of Wisconsin-Madison
327 Bascom Hall - 500 Lincoln Drive
Madison, WI 53706-1380

Dear Dr. Mellon,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 16, 2008 letter reporting instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin-Madison, following up on an initial telephone report on February 6, 2008. According to the information provided, OLAW understands that various rodents died due to lack of food and water on separate occasions. Specifically, eighteen rats died due to an automatic watering system failure, four sentinel mice died from dehydration, and two sentinel mice died from lack of food.

The corrective actions taken consisted of implementing new Standard Operating Procedures (SOP) addressing timely reporting of animal problems including revision of cards used to report sick and dead animals. All animal research technicians have been trained on the SOPs, counseled on performing daily animal health checks, and given flashlights to help with the cage checks. The problem with the automatic watering system has been fixed and the ventilated cage system was verified to be working correctly. A new staffing model for weekend care was implemented, the disciplinary process has been revised, two employees were reprimanded, and one was terminated.

Based on its assessment of these explanations and its review of the supporting documents, OLAW understands that the University of Wisconsin has implemented measures to correct and prevent recurrence of the problems. OLAW concurs with the actions taken by the University to comply with the PHS Policy. Your thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed about these matters and find no cause for further action by this Office.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: Eric Sandgren, Ph.D., IACUC Chair



April 16, 2008

APR 29 10:08 AM 9:34

Dr. Axel Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360
6705 Rockledge Drive, MSC 7982
Bethesda, MD 20892-7892

Dear Dr. Wolff:

This is a follow-up to a verbal report I made to you, regarding eighteen rats that died after an automatic watering system failed, four sentinel mice that died of dehydration, and two sentinel mice that died of lack of feed. The rats were on an NIH-funded study; the mice were not supported by NIH funding. The School of Medicine and Public Health (SMPH) Animal Care and Use Committee discussed these incidents at their December 2007, and January and February 2008 committee meetings.

Several changes have been made in response to the deaths of these animals. A standard operating procedure that had been in place since 2003 has now been updated. It was separated into two SOPs, to define timely reporting more clearly, and preventing reoccurrence of animal deaths due to unusual circumstances. The cards that care staff uses to report sick and dead animals have been updated by a team composed of animal operations and veterinary staff.

The Attending Veterinarian for SMPH and the Director of Laboratory Animal Resources (LAR) jointly discussed daily animal health checks with all animal research technicians in the unit. In addition, LAR training staff followed up with training on the updated standard operating procedures with all animal research technicians. In response to suggestions from animal research technicians, flashlights were purchased to assist with daily health checks. The automatic watering system is now supplied with acidified water to prevent lime-scale buildup, which was the underlying cause of the dehydration deaths.

In addition, a new staffing model has been designed and implemented for the weekend shifts that provides for greater accountability. A revised disciplinary process has been agreed upon with the SMPH human resources department. Normally discipline in the SMPH is a five-step process. Now, when the issues involve animal abuse or neglect the process can be reduced to two steps. The Associate Director of SMPH has communicated this change to all employees. As a result, two employees received letters of notice in their personnel files, and one employee was terminated.

Graduate School

Bascom Hall University of Wisconsin-Madison 500 Lincoln Drive Madison, Wisconsin 53706-1380

Deans' Office
608/262-1044
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**Graduate Admissions & Academic
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Dr. Axel Wolff, MS, DVM

April 16, 2008

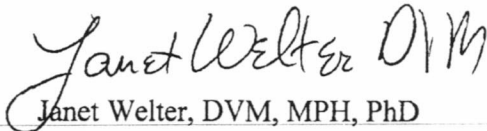
Page 2

In February, an engineer from the ventilated cage manufacturer visited the vivarium where the mice died to verify that the number of air exchanges in the ventilated cages was accurate, as we thought that the animals might be drinking more water than expected due to excessive air exchanges within the cage. The rate of air exchange is correct.

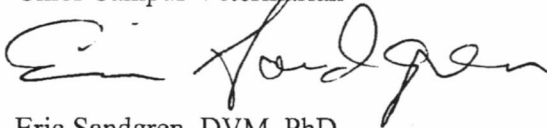
Finally, for your information, the Director of Laboratory Animal Resources in SMPH has announced his retirement effective August 1, 2008. The Associate Director is now managing day-to-day operations during the interim.

If you have further questions or concerns, please contact Dr. Janet Welter at 608/265-2695.

Sincerely,



Janet Welter, DVM, MPH, PhD
Diplomate ACLAM
Chief Campus Veterinarian



Eric Sandgren, DVM, PhD
Director, Animal Care and Use Program



William S. Mellon, PhD
Associate Dean for Research Policy

Enclosures (standard SOP and two new SOPs; reporting card)

UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH
LABORATORY ANIMAL RESOURCES

Standard Operating Procedure

NUMBER: 201

EFFECTIVE DATE: February 18, 2008

TITLE: Identifying and Reporting All Sick, Injured, or Dead Mice, Rats and Zebra fish

ATTACHMENTS: Flow Charts #1 and #2

Animal Research Technicians (ARTs) are responsible for observing every animal in the facility, that they are assigned to, on at least a daily basis and reporting all sick, injured, abnormally behaving and dead animals that they find, including protocol related problems. If animals are housed outside the LAR (Laboratory Animal Resources) animal facility in satellite facilities, research staff is responsible for observing the animals on at least a daily basis and reporting sick, injured, abnormally behaving and dead animals to the veterinary staff. More frequent observations may be necessary following surgery or when animals are known to be unhealthy or at high risk for problems arising.

1. Reporting Sick or Injured Mice and Rats:

1.1. Weekend, Holiday, and after hours - Emergencies and Non Emergencies: Notify the veterinary staff immediately (*i.e.* prior to completing the card) via the veterinary technician on call phone list or the UW Hospital Message Center at 608.262.2122 if you find a sick or injured mouse, rat or zebra fish. Also notify the investigator via phone, pager or email. Then follow instructions beginning at 1.3.1. below.

1.2. Weekday Emergencies: Notify the veterinary staff immediately (*i.e.* prior to completing the card) via phone. Also notify your supervisor and the investigator via phone, pager or in person. Then follow instructions beginning at 1.3.1. below.

1.3. Non-Emergencies - Weekdays: Follow these instructions.

1.3.1. Fill out a Sick/Dead Animal Card (SDAC) completely as soon as you find the animal.

1.3.2. Place the **yellow** and **pink** copies on the cage.

1.3.3. Give the **white** copy to the lead technician of that area or put it in the designated drop box.

1.3.4. Notify the investigator of a non-emergency via phone or email or the lead technicians can copy the investigators on the portion of the Daily Animal Health Report that pertains to them.

1.3.5. Weekdays: Before 1pm the lead technician will compile the information from all SDACs received that day, enter it into a Daily Animal Health Report and send it to the vet staff at vetstaff@mailplus.wisc.edu. The report can be sent more than once per day if desired.

1.3.6. Weekends and Holidays: The lead technician will compile the information from the SDACs filled out on weekends and holidays, enter it into the Daily Animal

NUMBER: 201

EFFECTIVE DATE: February 18, 2008

TITLE: Identifying and Reporting All Sick, Injured, or Dead Mice, Rats and Zebra fish

Health Report, and send it to the vet staff at vetstaff@mailplus.wisc.edu before 1pm the next business day.

1.3.6.1. The Daily Animal Health Report must include at least the date, facility, room, protocol, PI Lab name, species, ID number (if applicable), and what the observation was.

1.3.7. Weekdays after 1pm: Any Sick/Dead Animal Cards filled out after 1pm must be given to the lead technician immediately. The person who filled out the SDAC or the lead technician is required to contact the vet staff via phone immediately. The lead technician can send the information from these SDACs in a Daily Animal Health Report that same day or before 1pm the next business day.

1.4. The veterinary staff will mark the SDAC describing the problem or solution if continued monitoring or treatment is warranted. Treatment Cards may be placed on the cage by the veterinary staff if needed. When the problem is resolved all cards will be removed by the veterinary staff.

1.5. The veterinary staff is responsible for coordinating with the investigator regarding the clinical care and management of the animal.

2. Reporting Dead Mice and Rats:

2.1. On weekdays, weekends, and holidays: Fill out a Sick/Dead Animal Card (SDAC) completely as soon as you find the dead mouse or rat.

2.2. Place the **yellow** copy on the cage if there are still animals in that cage. If that was the only animal in that cage you can leave the yellow and pink copies together.

2.3. Give the **white** copy to the lead technician of that area or place it in the designated drop off box for the lead technician.

2.4. Notify the investigator about the death via phone, pager or email that same day. During weekdays (non weekend or holiday), copying the investigator on the portion of the Daily Animal Health Report that pertains to them will be considered notification.

2.5. The lead technician will enter the information from SDACs into the Daily Animal Health Report on a daily basis and send it to the vet staff at vetstaff@mailplus.wisc.edu. Any SDACs filled out on weekends and holidays will be entered into the Daily Animal Health Report and be emailed to the vet staff the next business day before 1pm.

2.6. Place the animal in a sealed plastic bag and place it in the necropsy cooler (or freezer if there is no cooler). The **pink** copy of the SDAC can either be placed in the bag with the animal OR attached to the outside of the bag/box. The investigator's name, the room, and date on the SDAC should be clearly visible either through the plastic bag or when attached to the bag/box. Fill out a disposal form if needed.

2.7. Weekdays, weekends and holidays: When any rodents are found dead, including sentinel animals, under unusual circumstances (i.e. multiple or unexpected deaths, water or food missing) keep the cage and all the parts intact and immediately notify the vet staff, investigator and supervisor by phone or pager. Call the UW Hospital Message Center at 608.262.2122 if it occurs on a weekend, holiday or after hours.

- 2.7.1. The vet staff will investigate the circumstances of the deaths. If it is determined that the deaths are unusual, the vet staff will inform Jim Goodrich, Jim Southard, Mike Gallardo, and Tom Kenney as soon as possible.
- 2.7.2. The vet staff designee will investigate the deaths in a timely manner and report the findings to the individuals involved. Those individuals will decide whether a procedural change, training or process improvement needs to take place.

3. Disposition of Sick/Dead Animal Cards:

- 3.1. The veterinary technicians will file Sick/Dead Animal Cards after the problem is resolved.
- 3.2. For rodents that do not have an individual clinical record, the Sick/Dead Animal Card will become the clinical record for the animal. Observations and treatments can be recorded on the SDAC or an additional Treatment Card until the problem is resolved. Any post-mortem observations may also be recorded on the SDAC or attached sheet. Documents associated with each case shall be filed chronologically by species and saved for 3 years.
- 3.3. The veterinary staff will monitor animal health using the information the leads provide in the Daily Animal Health Reports.

4. For Research Staff Reporting Sick, Injured or Dead Mice and Rats Housed outside an LAR Animal Facility

- 4.1. **Emergencies:** Notify the veterinary staff and the PI immediately (*i.e.*, prior to completing the Sick/Dead Animal Card) via phone or pager if it is an emergency or the animal is in obvious pain or distress.
- 4.2. **Weekends and Holidays**
 - 4.2.1. **Sick or injured animals:** Notify the on call veterinarian via the UW Hospital Message Center at 608.262.2122 if you find a sick or injured animal. Follow the steps beginning at 4.4.
 - 4.2.2. **Dead animals:** Follow steps beginning with 4.4 and notify the vet staff the next business day in your Daily Animal Health Report (see 4.4.1.1)
- 4.3. **Weekdays**
 - 4.3.1. **Sick or injured animals:** Notify the veterinarian by phone if you find a sick or injured animal. Follow the steps beginning at 4.4.
 - 4.3.2. **Dead animals:** Follow steps beginning with 4.4. and notify the vet staff the next business day in your Daily Animal Health Report (see 4.4.1.1)
- 4.4. Fill out a Sick/Dead Animal Card (SDAC) completely as soon as you find the animal.
 - 4.4.1. Keep the **white** copy for your records.
 - 4.4.1.1. On a daily basis, when Sick/Dead Animal Cards have been filled out, send a Daily Animal Health Report (summary of the information from the white copy) to the veterinary staff. Information from SDACs filled out on the weekend can be sent the next business day. The following must be included

NUMBER: 201

EFFECTIVE DATE: February 18, 2008

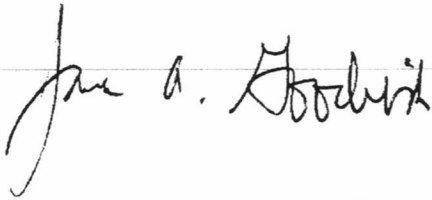
TITLE: Identifying and Reporting All Sick, Injured, or Dead Mice, Rats and Zebra fish

in the Daily Animal Health Report: date, facility, room, protocol, PI name, species, ID number (if applicable), and what the observation was.

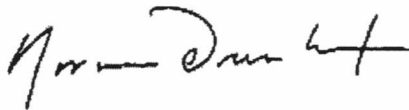
4.4.2. For sick or injured animals place the **yellow** copy on the cage.

4.4.3. For dead animals, if there are animals still in the cage, leave the **yellow** copy on the cage. (If that was the only animal in that cage you can leave the yellow and pink copies together.) Place the **pink** copy in the bag with the animal or attach it to the bag/box. The investigator's name, the room and date should be clearly visible on the SDAC. Place the animal in the refrigerator (or freezer if there is no refrigerator). Fill out a disposal form if needed.

4.5. **Weekdays, weekends and holidays:** When any mice and rats are found dead, including sentinel animals, under unusual circumstances (*i.e.* multiple or unexpected deaths, water or food missing), keep the cage and all parts intact and notify the vet staff and investigator by phone or pager immediately. Call the UW Hospital Message Center at 608.262.2122 if it occurs on a weekend, holiday or after hours.



Jim Goodrich, DVM
Senior Program Veterinarian, LAR-SMPH



Norman Drinkwater, PhD
Director, McArdle Laboratory



Jim Southard, PhD
Director, Laboratory Animal Resources

UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH
LABORATORY ANIMAL RESOURCES

Standard Operating Procedure

NUMBER: 210

EFFECTIVE DATE: February 18, 2008

TITLE: Identifying and Reporting All Sick, Injured, or Dead Non-Rodents, Hamsters and Chinchillas

ATTACHMENTS: Flow Charts #1 and #2

Animal Research Technicians (ARTs) are responsible for observing every animal in the facility, that they are assigned to, on at least a daily basis and reporting all sick, injured, abnormally behaving and dead animals that they find, including protocol related problems. If animals are housed outside the LAR (Laboratory Animal Resources) animal facility in satellite facilities, research staff is responsible for observing the animals on at least a daily basis and reporting sick, injured, abnormally behaving and dead animals to the veterinary staff. More frequent observations may be necessary following surgery or when animals are known to be unhealthy or at high risk for problems arising.

1. Reporting Sick or Injured Non-Rodents:

- 1.1. Weekends, Holidays, and after hours:** Notify the veterinary staff immediately (*i.e.* prior to completing the card) via the veterinary technician on call phone list or the UW Hospital Message Center at 608.262.2122, if you find a sick or injured non-rodent or hamster. Also notify the investigator via phone, pager or email. Then follow instructions beginning at 1.2.1. below.
- 1.2. Weekdays:** Notify the veterinary staff immediately (*i.e.* prior to completing the card) via phone if you find a sick or injured Non-Rodent. Also notify the investigator via phone, pager or email. Then follow instructions beginning at 1.2.1. below.
 - 1.2.1.** Fill out a Sick/Dead Animal Card (SDAC) completely after you have notified the Veterinary staff and investigator.
 - 1.2.2.** Place the **yellow** and **pink** copies on the cage or in the room logbook if there is no place to put the card on the cage/enclosure.
 - 1.2.3.** Give the **white** copy to the lead technician of that area or put it in the designated drop box.
 - 1.2.4. Weekdays: Before 1pm** the lead technician will compile the information from all SDACs received that day, enter it into a Daily Animal Health Report and send it to the vet staff at vetstaff@mailplus.wisc.edu. The report can be sent more than once per day if desired.
 - 1.2.5. Weekends and Holidays:** The lead technician will compile the information from the SDACs filled out on weekends and holidays, enter it into the Daily Animal Health Report, and send it to the vet staff at vetstaff@mailplus.wisc.edu before 1pm the next business day.

- 1.2.5.1. The Daily Animal Health Report must include at least the date, facility, room, protocol, PI Lab name, species, ID number (if applicable), and what the observation was.
 - 1.2.6. **Weekdays After 1pm:** Any Sick/Dead Animal Cards filled out after 1pm must be given to the lead technician immediately. The person who filled out the SDAC or the lead technician is required to contact the vet staff via phone immediately. The lead technician can send the information from these SDACs in a Daily Animal Health Report that same day or before 1pm the next business day.
 - 1.3. The veterinary staff will mark the SDAC describing the problem or solution if continued monitoring or treatment is warranted. Treatment cards may be placed on the cage or in the logbook by the veterinary staff if needed. When the problem is resolved all cards will be removed by the veterinary staff.
 - 1.4. The veterinary staff is responsible for coordinating with the investigator regarding the clinical care and management of the animal.
- 2. Reporting Dead Non Rodents:**
- 2.1. **Weekends, Holidays and after hours: Notify the veterinary staff immediately** (*i.e.* prior to completing the card) via the UW Hospital Message Center at 608.262.2122, if you find a dead Non-Rodent. Also notify the investigator via phone or pager. Then follow instructions beginning at 2.2.1. below.
 - 2.2. **Weekdays: Notify the veterinary staff immediately** (*i.e.* prior to completing the card) via phone if you find a dead Non-Rodent. Also notify your supervisor and the investigator via phone, pager or in person. Then follow instructions beginning at 2.2.1. below.
 - 2.2.1. Fill out a Sick/Dead Animal Card (SDAC) completely after you have notified the vet staff and investigator.
 - 2.2.2. Place the **yellow** copy on the cage/enclosure.
 - 2.2.3. Give the **white** copy to the lead technician of that area or place it in the designated drop off box for the lead technician.
 - 2.2.4. The lead technician will enter the information from SDACs into the Daily Animal Health Report on a daily basis and send it to the vet staff at vetstaff@mailplus.wisc.edu. Any SDACs filled out on weekends and holidays will be entered into the Daily Animal Health Report and be emailed to the vet staff the next business day before 1pm.
 - 2.2.5. The veterinary staff will direct the disposal of dead non-rodent animals.
 - 2.2.6. The vet staff will investigate the circumstances of the death. If it is determined that the death was unusual, the vet staff will inform Jim Goodrich, Jim Southard, Mike Gallardo, and Tom Kenney as soon as possible.
 - 2.2.7. The vet staff designee will investigate the death in a timely manner and report the findings to the individuals involved. Those individuals will decide whether a procedural change, training or process improvement needs to take place.

3. Disposition of Sick/Dead Animal Cards:

- 3.1. The veterinary technicians will file Sick/Dead Animal Reports after the problem is resolved.
- 3.2. Sick/Dead Animal Cards may be placed in the animal's individual clinical record. Observations and treatments will be recorded on the SDAC or the attached sheet/record until the problem is resolved. Completed SDACs shall be filed chronologically by species and saved for 3 years.
- 3.3. The veterinary staff will monitor animal health using the information the leads provide in the Daily Animal Health Reports.

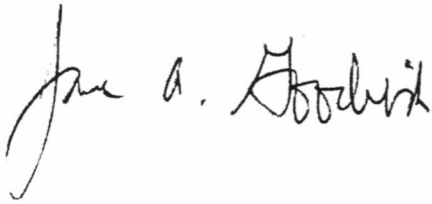
4. For Research Staff Reporting Sick, Injured or Dead Non-Rodents that are Housed Outside an LAR Animal Facility

- 4.1. **Emergencies:** Notify the veterinary staff and the PI immediately (*i.e.*, prior to completing the SDAC) via phone or pager if it is an emergency or the animal is in obvious pain or distress. Continue on to section 4.4.
- 4.2. **Weekends and Holidays:** Notify the on call veterinarian via the UW Hospital Message Center at 608.262.2122 if you find a sick, injured or dead non-rodent. Continue on to section 4.4.
- 4.3. **Weekdays:** Notify the vet staff and PI via phone or pager as soon as you find the animal and continue on to section 4.4.
- 4.4. Fill out a Sick/Dead Animal Card (SDAC) completely as soon as you find the animal.
 - 4.4.1. Keep the **white** copy for your records.
 - 4.4.1.1. On a daily basis, when Sick/Dead Animal Cards have been filled out, send a Daily Animal Health Report (summary of the information from the white copy) to the veterinary staff. The following must be included: date, facility, room, protocol, PI name, species, ID number, and what the observation was.
 - 4.4.2. For sick or injured animals place the **yellow** copy on the cage.
 - 4.4.3. The veterinary staff will direct the disposal of non-rodent animals that are found dead. If you are directed to place the animals in the freezer, the **yellow** copy of the SDAC will remain on the cage and the **pink** copy can be placed either in the bag with the animal or attached to the bag/box. The investigator's name, the room and date should be clearly visible on the SDAC. A disposal form will be filled out if needed.

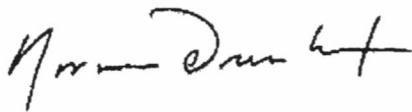
NUMBER: 210

EFFECTIVE DATE: February 18, 2008

TITLE: Identifying and Reporting All Sick, Injured, or Dead Non-Rodents and Hamsters



Jim Goodrich, DVM
Senior Program Veterinarian, LAR-SMPH



Norman Drinkwater, PhD
Director, McArdle Laboratory



Jim Southard, PhD
Director, Laboratory Animal Resources

A 3368-1M



Initial Report of Noncompliance

Date: 2/6/08

Time: 10:30

Name of Person reporting: Janet Welton
 Telephone #: 608 265 2659
 Fax #:
 Email:

Name of Institution: U of Wisconsin - Madison
 Assurance number: A 3368

Did incident involve PHS funded activity? _____
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened?

*Spontic lack of food + water
 Problem w/ care staff supervision*

Species involved: *Mice + rats*
 Personnel involved:
 Dates and times:
 Animal deaths: *20*

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
 Case # _____