

Facility Inspections



OLAW Online Seminar

June 28, 2018

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Animal Care and Use Program Facility Inspections

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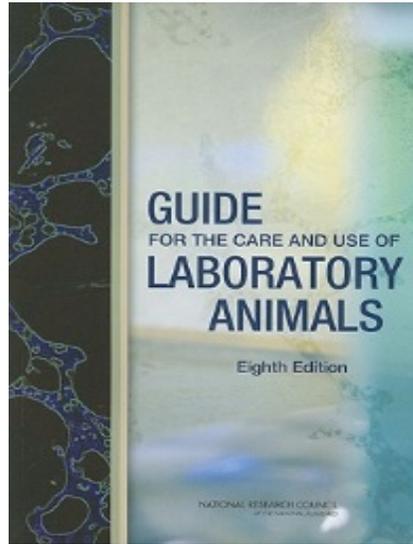
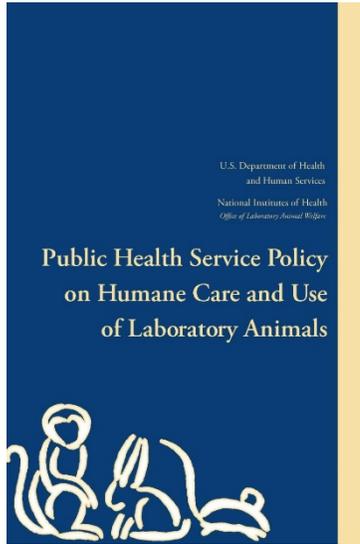
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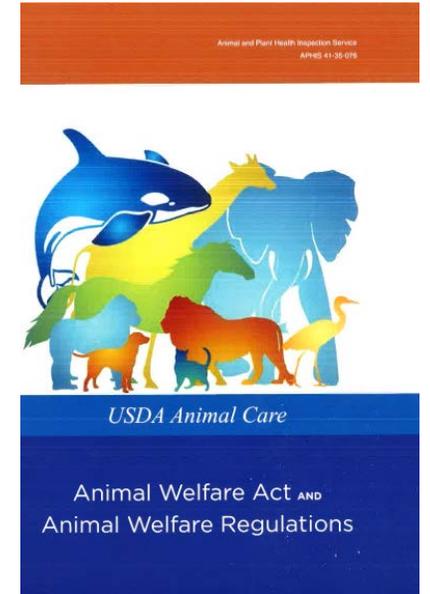
Where to Start?

What Should We Follow?

Alphabet Soup of Guidance Documents, Regulatory Bodies, and Accreditation Association Materials



National Institutes of Health
Office of Laboratory Animal Welfare



Throughout the Webinar

Dawn will describe the model used by the University of Michigan (U-M) to conduct facility inspections on **white** slides.

Bill will discuss alternative processes for conducting inspections that have been employed by other institutions across the country and the specific regulatory requirements they address on **grey** slides.

U.S. Department of Health
and Human Services

National Institutes of Health
Office of Laboratory Animal Welfare

Public Health Service Policy on Humane Care and Use of Laboratory Animals



Important Note

Footnote 8, PHS Policy

*The IACUC may, at its discretion,
determine the best means of
conducting an evaluation of the
institution's programs and
facilities. p.12*

i.e.,

Flexibility!

U-M Large Biomedical Program

The U-M process was designed to satisfy the biomedical research needs of a very large university.

U-M demographics:

1. 406,000 sq. ft. of IACUC approved animal space;
2. 975 approved animal care and use protocols; and
3. 600 principal investigators.

Areas Inspected at U-M

- **Locations**
 - Three campuses with dedicated vivaria, and
 - Field stations (when active)
- **Animal facilities**
- **Locations where procedures are conducted on live animals**
 - PI laboratory areas
 - Unit for Laboratory Animal Medicine (ULAM) procedural areas that are shared by PIs
 - Dedicated operating rooms for USDA covered species
- **Support areas**
 - Cage wash (clean and dirty side)
 - Animal receiving/dock and animal transportation vehicles
 - Storage areas (i.e., food, bedding and equipment storage)
 - Miscellaneous rooms (i.e., necropsy, radiology and pharmacy)
 - Other areas used to support the animal care and use program

What does the IACUC need to inspect?

Standards

- **PHS Policy:** *All of the institution's animal facilities including satellite facilities...* p.12
- **Guide:** *...inspect animal care and use facilities, including sites used for animal surgeries... p.34*
- **AWAR:** *...inspect all of the research facility's animal facilities, including animal study areas... p.57*

Definitions:

- **Facilities:** *Any and all buildings, rooms, areas, enclosures, or vehicles, including satellite facilities, used for animal confinement, transport, maintenance, breeding, or experiments inclusive of surgical manipulation. PHS Policy p.8*
- **Animal Study Area:** *...any building room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours. AWAR p.39*

What is a Satellite Facility? A Study Area?

- PHS Policy: ...*any containment outside of a core facility or centrally designated or managed area in which animals are housed for more than **24** hours.*
- AWAR: ...*containment outside of a core facility or centrally designated or managed area in which animals are housed for more than **12** hours.*
- Examples:
 - Remote laboratories and/or animal housing locations
 - Locations that are outside of a centrally managed facility
 - Covered components (i.e., offsite locations) where animal activities are subcontracted

What Facilities Must IACUC Oversee and Inspect?

- Animal housing (e.g., terrestrial, aquatic)
- Support areas (e.g., pharmacies, feed preparation and storage, diagnostics, animal receiving and transportation)
- Cage wash (both dirty and clean side)
- Surgery suites and related areas (e.g., surgeon prep, animal prep, recovery areas)
- Procedure areas (e.g., imaging, hazard containment, radiation, behavior testing areas)

IACUC Facility Inspections U-M

- Inspections are announced, and
- Conducted semiannually.
 - Conducted in spring and fall during two 5 week periods
 - U-M facilities are divided into 31 inspection areas that include more than 1400 locations

Timing of Facility Inspections

Each animal facility must be inspected every six months:

- Dedicated time period every six months, or
- A rolling inspection process.

Who is on the Inspection Team U-M?

- **2-3 person inspection teams**

- 2 voting committee members for all inspection teams, and
 - at least one member experienced in the species housed at the location and sometimes
- 1 Animal Care and Use Office staff member

- **Location representative**

- Unit for Laboratory Animal Medicine (ULAM) husbandry supervisor (for locations within the vivarium).
- PI or lab staff representative (for locations outside the vivarium).

Strategies to Facilitate Inspections at U-M

- Include additional inspection team members to provide expertise, continuity, and support:
 - Animal Care and Use office staff
 - Environmental Health and Safety staff
 - Veterinary staff
- Provide a copy of the previous inspection report to:
 - Ensure past deficiencies aren't recurring,
 - Reference previously inspected locations, and
 - Record current findings.
- Provide copies of the relevant federal standards.

Who is on the Inspection Team?

Remember: PHS Policy – footnote 8

Regulatory requirement

- USDA requires at least two IACUC members for inspection of areas that involve the use of covered species.
- PHS Policy provides flexibility for IACUCs to decide the best means of conducting the evaluation of facilities.

Preferences

- One or two IACUC members (2 are required for USDA)
- Environmental health and safety staff
- Staff members representing physical plant
- Post approval monitor
- Compliance staff professionals (i.e., IACUC administrators)
- A veterinarian

What You Need to Know Prior to the Inspection

Start with the ANIMALS...



...and work to the WALLS

What Do U-M Inspection Teams Assess?

- Animal well-being
- Primary enclosures
- Environmental conditions
- Physical plant
- Housekeeping, disinfection, and sanitation
- Food, water, bedding, drugs, and other supplies
- Euthanasia, carcass storage and disposal
- Labels, signage, and records
- Discuss personnel training, compliance, and safety

What Should be Assessed by the Inspection Team?

Priority!

The health and well-being of the animals. [How do they look?](#)

In general:

- Physical plant (e.g., location, construction standards, illumination and HVAC)
- Enclosures (e.g., cage sizes, cleanliness, social housing, enrichment)
- Surgical suites (e.g., adequate equipment support and resources)
- Procedure areas (e.g., cleanliness, drug storage and sanitation practices)

And:

- Food, water and bedding (e.g., availability of food and water, species appropriate bedding)
- Sanitation, waste disposal, pest control, and emergency management
- Records maintenance

How Does U-M Classify Inspection Findings?

- No Findings
 - Animals are healthy
 - General aspect of the facility are compliant with regulations
- Deficiencies
 - Conditions not consistent with *Guide/AWAR* expectations
 - Animal welfare issues are reported immediately!

Reference for IACUC Members: a checklist that's provided prior to inspections

How Does U-M Classify Inspection Findings?

Suggestions For Improvement

- Conditions or circumstances not considered deficiencies, but enhancements that could improve overall program quality

Notes

- Comments intended as reminders for ACU staff when preparing for subsequent inspections

Reference for IACUC Members: a checklist that's provided prior to inspections

Classification of Findings

Deficiencies

- **Significant** (is or may be a threat to the health or safety of animals or humans)
 - Nonfunctional life sustaining equipment (e.g., HVAC, automatic watering systems)
 - Conducting unapproved animal activities
- **Minor** (doesn't require an immediate solution to protect life/prevent distress)
 - Room maintenance (e.g., peeling paint, rusting surfaces, room clutter)

Inspecting Satellites vs. Vivaria

- Satellite Facilities
 - Inspected with 2-3 person team or
 - Live video feeds with audience of at least 2 voting members
- Vivaria
 - Inspection with 2-3 person team
 - May split up in the same facility and consult when complete

Note: Environmental Health and Safety is made aware of and accompanies most inspections.

Conducting the Inspections

“The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution’s programs and facilities.” **Footnote 8, the PHS Policy (Page 12)**

Ideas for flexibility ([Key – at the IACUC’s discretion](#))

1. At a minimum, two IACUC members visit each facility (compliant with the AWAR)
2. At least two IACUC members visit a facility but within the facility they may individually inspect specific rooms or areas with the ability to consult each other if necessary (compliant with AWAR)
3. IACUC Service Staff (e.g., PAMs, administrators and veterinary technicians) inspect euthanasia only, and tissue collection areas, and report the findings to the IACUC. The IACUC inspects the remaining areas. (not applicable for areas under AWAR)
4. Satellite facilities are inspected using video or other streaming technology preferably live during an IACUC meeting (compliant with AWAR)
5. For subcontracted animal facilities, organizations may use Memorandums of Understanding to ensure the inspection requirement is satisfied

Questions



Question 1

Q: To my knowledge, there is no mandate as to the frequency of calibration of isoflurane vaporizers, only recommendations based on manufacturer's specs and best practices.

During facilities inspections, we find vaporizers with no calibration stickers or other signs that they have been recently (or ever) checked.

What incentive is there for PIs to send their units out for calibration when it is not required in the *Guide*? Any advice on getting PIs to follow manufacturer's specs and best practices?

Question 2, Part 1

Q: How much flexibility does OLAW allow in the conduct of semiannual inspections? If my institution inspects Building A on January 15th, when does OLAW expect the next semiannual inspection of Building A to occur?

A: Approximately 6 months later, and no later than 30 days after July 15th.

First Inspection Date	Ideal 2 nd Inspection Date	Permitted 2 nd Inspection Date Range
January 15, 2018	July 15, 2018	As late as August 14, 2018

Question 2, Part 2

Q: How much flexibility does OLAW allow in the conduct of semiannual inspections using a rolling inspection process?

A: The 2nd inspection for each site must be approximately 6 months after the 1st inspection, and no later than 6 months and 30 days after the 1st.

Bldg.	First Inspection Date	Ideal 2 nd Inspection Date	Permitted 2 nd Inspection Date Range
A	January 15, 2018	July 15, 2018	As late as August 14, 2018
B	January 30, 2018	July 30, 2018	As late as August 29, 2018
C	February 15, 2018	August 15, 2018	As late as Sept 14, 2018
D	March 1, 2018	September 1, 2018	As late as Sept 30, 2018
E	March 15, 2018	September 15, 2018	As late as Oct 14, 2018

Question 3

Q: There are many other locations not used for housing or animal work in our facility, such as laundry rooms, offices for the animal care staff, showers, and staff break rooms. These spaces are contiguous spaces to the facility. Should they be included in the inspection?

What is considered a functional area? Should they be inspected? If so, how and to what level?

Question 4

Q: A PI needs to transport rodents to a nearby institution for specialized MRI procedures. Unfortunately the transports must occur outside the university's animal transport service hours.

Is the IACUC required to conduct semiannual inspection of the personal vehicles used for transporting these animals?

Question 5

Q: A PI is conducting a study that involves client-owned animal that are housed in the owners' homes. Is the IACUC required to inspect the owners' homes to ensure the IACUC-approved protocol is being followed?

Question 6

Q: Since an area used only for euthanasia doesn't necessarily fall under the PHS definition of facilities, do euthanasia areas need to be inspected semi-annually? Or can the IACUC establish other means for inspecting/overseeing these areas?

Question 7

Q: Could the IACUC authorize a compliance office staff member (e.g., PAM person or IACUC Administrator) to conduct facility inspections, and only require that staff member to report back to the IACUC when identified deficiencies aren't resolved?

Question 8

Q: If the IACUC is going to authorize non-committee members to do inspections, how should this authorization be documented?

Monitoring for Humane Endpoints: Developing an Appropriate Strategy



OLAW Online Seminar
September 20, 2018

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