

IACUC	SOP:	TAMU-S-010	Title:	Semiannual Facility Inspections and IACUC Oversight of Animal Use Locations
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Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	09/01/2024	8/31/2027
Houston	03/01/2023	01/31/2026

1. PURPOSE

- 1.1. To describe the process for conducting semiannual inspections of animal facilities, satellite housing and surgical locations overseen by the IACUC
- 1.2. To describe the process for conducting IACUC oversight of locations that do not require semiannual inspection under federal regulation

2. SCOPE

- 2.1. This SOP applies to:
 - 2.1.1. Locations under the oversight of the IACUC
 - 2.1.2. The semiannual inspection of animal facilities, satellite locations, and animal study areas where surgery is performed
 - 2.1.3. IACUC oversight of animal study areas where activities occur that may be exempted from semiannual inspection as defined in federal regulation
- 2.2. The initial inspection of animal facilities and study areas is not addressed in this SOP. Refer to TAMU-S-016 for more information.
- 2.3. Does not include inspection of personal vehicles used to transport non-USDA regulated species. See TAMU-G-016.

3. **RESPONSIBILITY**

- 3.1. **IACUC Members** are responsible for conduct of semiannual inspection as described in TAMU-S-006 and this document.
- 3.2. The **IACUC** is responsible for determining the best means of evaluating the institution's animal study areas and facilities, including the use of ad hoc consultants in the performance of evaluations; determining the appropriate schedule and mechanism for performing oversight of areas not required to be inspected semiannually; performing the evaluation of the inspection and oversight findings to evaluate compliance with applicable regulations and guidelines; establishing a reasonable and specific plan and schedule for correcting identified deficiencies; and reporting the outcome of the evaluation to the IO.
- 3.3. The **IO** is responsible for reviewing significant deficiencies and serious or continuing noncompliance reports from the IACUC and taking appropriate action, which may include temporarily halting on-going animal activities and reporting of incidents to the USDA, OLAW, AAALAC and the funding agency, as applicable.
- 3.4. The **AWO Staff** is responsible for the coordination and scheduling of inspection/oversight visits to animal study areas and housing facilities and preparing and maintaining inspection/oversight documents; including lists of locations, sample checklists or other documents used to facilitate the inspection and oversight process, documentation of the performance and outcome of the inspection/oversight process, including the report to the IO for semiannual inspections. Additionally, AWO staff will convey results of inspection and oversight findings to location contacts and follow-up as applicable on corrective actions taken.
- 3.5. Ad-hoc Consultants are responsible for conducting inspection or oversight as directed by the IACUC. Ad-hoc consultants may perform semiannual inspections or oversight visits along with IACUC members or autonomously; but may not replace the IACUC member for the inspection of locations covered by the USDA Registration with which the IACUC is affiliated.
- 3.6. **Principal Investigators, Principal Investigator Staff or Study Contacts,** and **Animal Facility Care Personnel** are responsible for assisting inspectors during an inspection, responding to inspection findings and noted deficiencies by the timeline for correction indicated by the IACUC.



DIVISION OF RESEARCH

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **AAALAC:** AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.
- 4.2. ACURO: Animal Care and Use Review Office of the United States Army Medical Research and Development Command.
- 4.3. **Ad-hoc Consultant**: Individual who is not an IACUC member, but who has sufficient training and experience to conduct an inspection or participate in programmatic review on behalf, and at the request, of the IACUC. Most often an experienced faculty member, veterinarian or AWO staff member. When ad hoc consultants are utilized, the IACUC remains responsible for the evaluation, determination of corrective action, and reporting of all findings.
- 4.4. **Ag Guide:** Guide for the Care and Use of Agricultural Animals in Research and Teaching. Primary reference document for meeting the needs and requirements of agricultural animals utilized in research and teaching.
- 4.5. Animal Activities: Activities with live vertebrate animal species, including research, teaching, and testing; as well as husbandry and/or maintenance of animals in support of these activities.
- 4.6. Animal Concern: Concern related to the care and use of animals at Texas A&M University. May be expressed verbally or in writing by a participant in the animal program, member of the institution, or general member of the public; and may be submitted anonymously or through a third party hotline. May require reporting to federal regulators and accrediting bodies
- 4.7. **Animal Facility:** Centralized vertebrate animal housing location managed by a Core Support unit. Includes vehicles owned by the facility used for live animal transport.
- 4.8. Animal Study Area: Location outside of a central animal facility where activities with live animals occur, inclusive of classroom spaces.
- 4.9. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly, and have delegated authority from, the AV ("AV designee").
- 4.10. AWO: Animal Welfare Office. Supports the IACUC administratively.
- 4.11. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.12. FCR: Full committee review. Review and formal vote performed by a convened quorum of the members of the IACUC as described in TAMU-S-002.
- 4.13. Field Study: A term in the AWAR relating to animal activities in covered species that "do no harm, are not invasive, and do not materially alter the behavior of the animal".
- 4.14. **The Guide:** The Guide for the Care and Use of Laboratory Animals. Primary reference document for meeting the needs and requirements of animals used in biomedical research. The PHS Policy requires institutions to use the Guide as a basis for developing and implementing an institutional program for activities involving animals.
- 4.15. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.16. **Initial Inspection**: Inspection of a location not currently under IACUC oversight, such as a new or renovated animal facility, new satellite location, or new animal study area. Includes inspection of a non-surgical procedure location currently under IACUC oversight that is proposed to be utilized for surgery.
- 4.17. **IO**: Institutional Official. Individual within the University with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of federal regulation.
- 4.18. Location Contact: Refers to individuals affiliated with animal facilities and animal study areas who may be contacted in reference to a semiannual inspection or oversight visit.



4.19. **Minor Deficiency**: Inspection or programmatic review finding which may be inconsistent with federal regulations but in the judgement of the IACUC does not represent a threat to the health or safety of the animals.

4.20. NASA: The National Aeronautics and Space Administration

4.21. **Noncompliance:** Accidental or intentional failure to comply with state and federal regulations, System policies or regulations, University rules or procedures, IACUC guidance, or the requirements to conduct research, teaching or testing using animals; including adherence to the approved animal use protocol. **Serious noncompliance** has a negative impact on the welfare of an animal and/or is in direct violation of a federal standard regulating animal activities, including provisions of the Occupational Health and Safety Program, and may require reporting to federal regulators, funding agencies and/or accrediting body bodies. (Also see Federal Notice NOT-OD-05-034 for examples of situations that constitute reportable noncompliance under the PHS Policy.)

4.22. NSF: National Science Foundation

- 4.23. **OLAW**: Office of Laboratory Animal Welfare. Provides guidance and interpretation of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (Policy) for PHS-funded research and monitors compliance with the Policy by Assured Institutions.
- 4.24. **PHS:** Public Health Service. Federal agency under the United States Department of Health and Human Services responsible for oversight of the PHS Policy.
- 4.25. **PHS Policy:** PHS Policy on Humane Care and Use of Laboratory Animals. Federal policy established by the Health Research Extension Act of 1985 and administered by OLAW.
- 4.26. **PI**: Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.27. SAI: Semiannual Inspection. See (Semiannual) IACUC Inspection.
- 4.28. Satellite Location: PI managed building, room, area, enclosure, or other containment where animals are housed or held outside of the primary housing location for over 12 hours (USDA regulated species) or 24 hours (non-USDA regulated species).
- 4.29. (Semiannual) IACUC Inspection: The inspection, at least semiannually, of the institution's animal facilities, satellite housing and animal study areas where surgery occurs.
- 4.30. SFI: Suggestion for improvement
- 4.31. **Significant Deficiency:** Inspection or programmatic review finding which is inconsistent with federal regulation and in the judgement of the IACUC and IO is or may be a threat to the health or safety of the animals.
- 4.32. **SOP:** Standard Operating Procedure. SOP documents are developed by the IACUC to provide procedural standards for the activities performed by the committee.
- 4.33. **Space:** For the purposes of this document, space indicates a room, cubicle, hallway, barn, pasture, paddock, pen or other structure or space which is distinct and definable by walls or fencing.
- 4.34. **Surgery**: Cutting into the body through the use of a tool such as a scalpel blade, surgical scissors, laser, or other suitable device. May also refer to an invasive measurement under anesthesia.
- 4.35. **USDA**: United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).
- 4.36. USDA Regulated: Species or activities which fall under the AWA/AWAR.

5. PROCEDURE

SEMIANNUAL INSPECTIONS (SAI)

- 5.1. Regulatory Requirements
 - 5.1.1. USDA Regulated: Animal facilities in which USDA regulated species are housed (exclusive of free-living wild animals in their natural habitat), as well as animal study areas where animals are maintained for 12



or more hours, and animal transport vehicles must be inspected at least once every six (6) months. twice a year, six (6) months apart. Inspections must be performed by at least two members of the IACUC₇ though qualified ad-hoc consultants may assist the IACUC members in the inspection. however Inspectors can may be deployed to perform inspections separately as determined by the IACUC as long as both members physically inspect the same space(s) once every six (6) months.

5.1.2. PHS Policy:

- 5.1.2.1. Animal facilities in which animals on PHS/NSF/NASA funded grants for which the PHS Policy applies are housed, vehicles owned by the facility used for animal transport, as well as animal study areas where animals are maintained for more than 24 or more hours, must be inspected at least once every six (6) months. twice a year, six (6) months apart. Qualified ad hoc consultants may conduct inspections on behalf of the IACUC.
- 5.1.2.2. Animal facilities and study areas in which animals on PHS/NSF/NASA funded grants for which the PHS Policy applies are used in surgical procedures must be inspected at least once every six (6) months. twice a year, 6 months apart. Qualified ad hoc consultants may conduct inspections.
- 5.1.3. Ag Guide: Animal facilities where agricultural animals used for agricultural activities are housed, as well as animal study areas, must be inspected twice a year to the standards of the Ag Guide. While not backed by federal regulation, the Ag Guide must be followed for agricultural animals used for agricultural research, teaching and testing as per TAMUS policy 15.99.07.
- 5.2. **Classification of Findings.** Classification of SAI findings as a significant or minor deficiency is based on the potential threat to the health or safety of the animals:
 - 5.2.1. Significant deficiencies include, but are not limited to:
 - 5.2.1.1. Inoperable heating, cooling, electrical or watering systems or failure of such systems sufficient to affect critical housing and operational areas
 - 5.2.1.2. Inadequate or lack of food and/or water leading to starvation or dehydration resulting in death or euthanasia of impacted animals
 - 5.2.1.3. Inadequate husbandry staffing such that animals are not cared for appropriately resulting in injury, illness, death or severe distress to animals
 - 5.2.1.4. PI conduct of unapproved animal activities
 - 5.2.2. Minor deficiencies include, but are not limited to:
 - 5.2.2.1. Problem for which an immediate solution is not necessary to protect life or prevent distress to animals; e.g.: chipped or peeling paint; minor cleanliness issues, expired compounds or materials stored in the general supply without indication of expired status that were not used in live animals or were used with prior IACUC approval (see TAMU-G-024)

5.3. Participation – IACUC Members

- 5.3.1. IACUC members will be notified when SAIs are to be conducted with sufficient time to request participation
- 5.3.2. No IACUC member wishing to participate in the inspection process will be excluded
- 5.3.3. IACUC members may not inspect their own animal study area(s)
- 5.3.4. IACUC members in the Veterinary membership role (see TAMU-S-006) are discouraged from performing inspection of animal facilities under their direct oversight

5.4. Participation – Ad Hoc Consultants

- 5.4.1. The IACUC will has determined when that it is appropriate to use qualified ad hoc consultants who are AV designees or members of the AWO to assist members (USDA regulated, non-USDA regulated), or in place of members (non-USDA regulated), for the inspection of any location. of locations used for non-USDA regulated species or activities in place of IACUC members Additional qualified ad hoc consultants may be identified by the IACUC or IACUC Chair.
- 5.4.2. When ad hoc consultants are utilized, the IACUC remains responsible for the evaluation, determination of corrective action, and reporting of all findings

5.5. Number of Inspectors

5.5.1. Locations with USDA regulated species or activities:



- 5.5.1.1. Inspections will be performed by at least two IACUC members
- 5.5.1.2. Inspectors must visit the same locations
- 5.5.1.3. Inspectors may visit separate facilities or locations
- 5.5.1.4. Inspections may be performed on different days as long as individual spaces are inspected at least once every six (6) months
- 5.5.2. For all other locations, inspections may be conducted by at least one (1) IACUC member or ad hoc consultant

5.6. Location Selection (including transport vehicles)

- 5.6.1. Location inclusion Locations are included in the SAI when:
 - 5.6.1.1. The location is under the oversight of the IACUC; and
 - 5.6.1.2. The location has been utilized for animal activities for some period of the past six (6) months; and/or
 - 5.6.1.3. The location will (or is anticipated to) be utilized for animal activities for some period in the next six (6) months.
 - 5.6.1.4. Examples include:
 - 5.6.1.4.1. All animal facilities
 - 5.6.1.4.2. Animal study areas where surgery is performed
 - 5.6.1.4.3. Animal study area utilized for animals covered by the Ag Guide
 - 5.6.1.4.4. Satellite locations, including locations where USDA regulated wild species studied in their natural habitat are held in containment for 12 or more hours
 - 5.6.1.4.5. Vehicles owned by the facility used for animal transport
 - 5.6.1.4.6. Privately owned vehicles used to transport USDA regulated animals
- **5.6.2.** Location exclusion (including transport vehicles) Locations are excluded from SAI in the following instances:
 - 5.6.2.1. The location is not under the oversight of the IACUC:
 - 5.6.2.1.1. USDA inspected abattoir(s) not owned by the institution
 - 5.6.2.1.2. Private property that includes, but is not limited to, homes, businesses, feed lots and veterinary clinics, where the animals remain under the oversight of the owner
 - 5.6.2.1.3. Areas containing free-living wild animals in their natural habitat (where not covered by inclusion criteria)
 - 5.6.2.1.4. Areas where animals are housed and/or used but their housing/use does not require submission of an AUP
 - 5.6.2.2. The IACUC may determine that an animal study area covered by the IACUC may be exempted from the SAI process provided a regulatory or institutional requirement does not prohibit this determination. Oversight of such locations is as described below.
 - 5.6.2.2.1. Examples include, but are not limited to:
 - 5.6.2.2.1.1. Animal study areas where blood collection, injection, behavioral testing, imaging, or euthanasia occur
 - 5.6.2.2.1.2. Classrooms
 - 5.6.2.2.1.3. Private property where animals are owned by the institution and under the oversight of the IACUC, are housed for the purposes of the study for more than 12 hours (USDA regulated) or 24 hours (non-USDA regulated)
 - 5.6.2.3. The following vehicles used to transport animals are excluded from inspection:
 - 5.6.2.3.1. Commercial vehicles, including rental vehicles
 - 5.6.2.3.2. Privately owned vehicles used to transport non-USDA regulated animals

5.7. Inspection Timing

- 5.7.1. The IACUC will determine the most appropriate schedule to conduct inspections (options may be combined):
 - 5.7.1.1. Semiannual



- 5.7.1.1.1. Inspect all applicable locations during a dedicated time period at least once every six months
- 5.7.1.2. Rolling Schedule
 - 5.7.1.2.1. A portion of locations are inspected on a rolling schedule such that all applicable locations are inspected at least once every six months
- 5.7.2. Note: For either option, timing of inspections may extend 30 days beyond the six-month interval as long as no forward drift occurs from year to year.

5.8. Inspection Scheduling

- 5.8.1. IACUC members and ad hoc consultants:
 - 5.8.1.1. IACUC members are notified of inspection dates and locations and can volunteer to perform inspections or request ad hoc consultants be utilized (if applicable)
 - 5.8.1.2. AWO staff remind IACUC members and ad-hoc consultants about their upcoming inspections and provide inspection materials prior to the inspection
- 5.8.2. Location contacts:
 - 5.8.2.1. Announced inspections
 - 5.8.2.1.1. Inspections are scheduled in advance with location contacts by the AWO
 - 5.8.2.2. Unannounced inspections:
 - 5.8.2.2.1. The IACUC will determine when unannounced inspections are performed
 - 5.8.2.2.2. No prior notification to location contacts will be made in advance of the inspection **process**

5.9. Inspection Process

- 5.9.1. Inspector(s) may visit the facility, animal study location or transport vehicle in-person (USDA regulated, non-USDA regulated), or by utilizing virtual technology (non-USDA regulated). (live feed required for USDA regulated animals).
- 5.9.2. Additional flexibilities for inspection of facilities, animal study locations and transport vehicles utilized for non-USDA regulated animals may include review by inspector(s) of video(s), picture(s), written self-assessment(s) (or a combination thereof), as appropriate to the location and activity.
 - 5.9.2.1. Eligibility for participation and selection of flexible inspection modality to be determined by the inspector(s) in consultation with AWO staff.
 - 5.9.2.2. In-person or live feed video inspection may follow flexible inspection if the inspector(s) feels that insufficient information was available to perform an adequate review.
 - 5.9.2.3. Videos, pictures and written self-assessments will be deleted upon completion of IACUC review. These will not be maintained.
 - 5.9.2.4. Note: Locations (including vehicles) eligible for participation in the flexible semiannual inspection process are those in good standing with the IACUC. This may exclude PIs/facility managers who are not responsive to IACUC requests, require timeline extensions due to no response/inaction or have Substantiated Animal Concerns and incidents of Serious or Continuing Noncompliance.
- 5.9.3. AWO staff provides inspectors with materials appropriate for the particular location(s) to be inspected, such as:
 - 5.9.3.1. Checklist(s) to conduct the inspection to the relevant regulations and institutional standards for the particular location (see list in References)
 - 5.9.3.2. Basic information about the location and the most recent past inspection findings
- 5.9.4. Facility contacts, when available, escort the inspector(s) through inspection locations
 - 5.9.4.1. For virtual inspections, the facility contact is requested to walk inspectors through the facility virtually and allow the inspector to direct the areas, animals and materials viewed during the inspection
- 5.9.5. Inspection findings are documented in writing by the inspector(s) and/or AWO staff during the inspection

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- 5.9.6. SFIs, notes and comments relevant to the location or activities may be relayed verbally to the facility contact during the inspection or submitted to AWO staff for inclusion in the written communication post inspection
- 5.9.7. After completion of the inspection, findings are consolidated by AWO staff for inspector review
- 5.9.8. If an issue with animal welfare, potential significant deficiency, and/or potential continuing or serious noncompliance is discovered during the inspection or subsequent AWO staff or IACUC review of the inspection findings:
 - 5.9.8.1. The IACUC Chair and AV (or designees) are notified in a timely manner by either the inspector or AWO staff
 - 5.9.8.1.1. Note: The AV (or designee) is contacted during the inspection in the event that the health or well-being of an animal(s) is in immediate or on-going jeopardy
 - 5.9.8.2. Findings are reported to location contacts at the time of inspection, when possible and as applicable
 - 5.9.8.3. The IACUC Chair and/or AV (or designees) establish immediate corrective actions, as applicable, and determine if immediate notification to the IO, OLAW or USDA is required
 - 5.9.8.4. Potentially serious or continuing noncompliance identified during IACUC inspection is addressed as described in TAMU-S-012

5.10. IACUC Review

5.10.1. The IACUC will determine the most effective way to conduct the review of inspection findings and responses/corrective actions performed (may apply a mix of review methods for non-USDA regulated animals/facilities only):

5.10.1.1. Subcommittee:

- 5.10.1.1.1. Does not apply to inspection of USDA regulated animals and locations
- 5.10.1.1.2. Applicable to findings identified as minor deficiencies only
- 5.10.1.1.3. Performed by the IACUC member(s) who performed the inspection or the IACUC Chair (or designee) if the inspection was performed by an ad hoc consultant(s)
- 5.10.1.1.4. The subcommittee member(s) in their review of the draft inspection findings (described above) confirms the classification of the finding as minor, and sets a reasonable and specific plan and schedule for corrective action.
 - 5.10.1.1.4.1. AWO staff may suggest classification of findings, corrective actions and timetables for corrections to aid the IACUC
- 5.10.1.1.5. Relevant SFIs, notes, comments and findings, as well as the identified corrective actions and timetable for correction are distributed to location contacts in writing by the AWO
- 5.10.1.1.6. AWO staff confirm corrective actions are completed by the timetable for correction 5.10.1.1.6.1. Incomplete corrective actions are reported to the IACUC Chair (or
 - designee) for additional action as appropriate
- 5.10.1.1.7. The outcome of subcommittee review is presented to the full committee of the IACUC either at a convened meeting or through electronic distribution
- 5.10.1.2. Full committee:

5.10.1.2.1. Must be utilized findings for USDA regulated animals and locations

- 5.10.1.2.2. Applicable to findings identified as minor or significant deficiencies
- 5.10.1.2.3. Relevant initial SFIs, notes, comments and findings from the inspector, as well as suggested corrective actions developed by AWO staff may be submitted to location contacts in writing by the AWO prior to full committee review to encourage timely correction of issues.
- 5.10.1.2.4. Review is performed by the full committee of the IACUC either at a convened meeting of a quorum (USDA regulated) or through electronic distribution (non-USDA)
- 5.10.1.2.5. The IACUC classifies the findings as minor or significant, establishes a reasonable and specific plan and schedule for correcting each deficiency



- 5.10.1.2.5.1. AWO staff may suggest classification of findings, corrective actions and timetables for corrections to aid the IACUC
- 5.10.1.2.6. Relevant SFIs, notes, comments and findings, as well as the identified corrective actions and timetable for correction are distributed to location contacts in writing by the AWO
- 5.10.1.2.7. AWO staff confirm corrective actions are completed by the timetable for correction 5.10.1.2.7.1. Incomplete corrective actions are reported to the IACUC Chair (or

designee) for additional action as appropriate

- 5.10.2. Regardless of review method:
 - 5.10.2.1. The IACUC is notified by AWO staff when deficiencies are corrected to ensure all items are addressed as stipulated by the IACUC
 - 5.10.2.2. AWO staff maintain documentation of the IACUC inspection and review outcome on behalf of the IACUC as per TAMU-S-001

5.11. Overdue Inspection Findings

- 5.11.1. Any significant deficiency regarding USDA covered species remaining uncorrected beyond its timetable for correction must be reported in writing within 15 business days by the IACUC, through the IO, to APHIS and any federal agency funding that activity. Funding agency notification will occur through Sponsored Research Services at the direction of the IO.
- 5.11.2. Minor deficiencies remaining uncorrected beyond the timetable for correction may be reviewed by either the IACUC Chair (or designee) or the full committee of the IACUC to establish an appropriate course of action. Significant deficiencies are reviewed by the full committee of the IACUC at a convened meeting or through electronic distribution.

5.12. Re-Inspection:

- 5.12.1. Re-inspection of a location or activity will be scheduled at the discretion of the IACUC and may be announced or unannounced
- 5.12.2. The re-inspection process will follow the above steps utilized for the inspection process
- 5.12.3. Additional reporting to the IO of re-inspection results may occur at the request of the IO or the discretion of the IACUC

5.13. Reporting of Findings:

- 5.13.1. Inspection findings, regardless of review method, are reported to the IO every six months as a component of the report detailing the IACUC's semiannual programmatic review (see TAMU-S-011).
 - 5.13.1.1. For inspections performed on a rolling schedule: In addition to inclusion in the semiannual programmatic review report, the IO is provided with a separate notification of findings classified by the IACUC as significant to ensure that timely action is taken to address the deficiency.
- 5.13.2. The IACUC reports deficiencies determined to be programmatic failure or serious or continuing noncompliance through the IO, with a full explanation of the circumstances and actions, as a written report as applicable to AAALAC, OLAW and if applicable, ACURO and the USDA. This report will be prepared by AWO staff.
 - 5.13.2.1. Funding agency notification will occur through Sponsored Research Services at the direction of the IO.

OVERSIGHT

- 5.14. Location Inclusion Locations are included in the oversight process when:
 - 5.14.1. The location is under the oversight of the IACUC; and
 - 5.14.2. The location is excluded from the SAI process as described above; and
 - 5.14.3. The location is utilized for animal activities on a regular basis (continual or sporadic).
 - 5.14.4. Vehicles excluded from the SAI process may be included in the oversight process when requested by the IACUC

5.15. Timing

5.15.1. Locations will undergo oversight at least once annually



- 5.16. **Process** The IACUC will determine the most effective way to perform oversight (may apply a mix of methods):
 - 5.16.1. Inclusion of locations in the SAI process
 - 5.16.1.1. The following sections above apply to this process and will be performed as described above: Participation (IACUC Member, Ad Hoc Consultant), Number of Inspectors, Inspection Scheduling, Inspection Process, IACUC Review, Overdue Inspection Findings, Re-Inspection and Reporting of Findings with the following modification:
 - 5.16.1.1.1. Locations with USDA regulated species may be visited by a single IACUC member or ad hoc consultant
 - 5.16.1.2. AWO staff will be responsible for ensuring locations are included in the list of locations to visit during the applicable SAI
 - 5.16.2. Performance of oversight outside of the SAI process
 - 5.16.2.1. The following sections above apply to this process and will be performed as described above: Participation (IACUC Member, Ad Hoc Consultant), Number of Inspectors, Inspection Scheduling, Inspection Process, IACUC Review, Overdue Inspection Findings, Re-Inspection and Reporting of Findings with the following modification:
 - 5.16.2.1.1. Locations with USDA regulated species may be visited by a single IACUC member or ad hoc consultant
 - 5.16.2.2. AWO staff will be responsible for ensuring locations are visited on the schedule established in this document

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. Regulatory resources:
 - 6.1.1. USDA Animal Welfare Regulations 9 CFR Ch.1 Subpart C § 2.31
 - 6.1.2. PHS Policy on Humane Care and Use of Laboratory Animals
 - 6.1.3. USDA Animal Welfare Inspection Guide
 - 6.1.4. Guide for the Care and Use of Laboratory Animals
 - 6.1.5. Guide for the Care and Use of Agricultural Animals in Research and Teaching
 - 6.1.6. <u>OLAW NOT-OD-05-034</u> Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals
 - 6.1.7. OLAW NOT-OD-21-164
 - 6.1.8. <u>OLAW NOT-OD-24-075</u> Guidance on Flexibilities for Conducting Semiannual Inspections of Animal Facilities
 - 6.1.9. <u>OLAW NOT-OD-24-076</u> Guidance on Flexibilities for Conducting Semiannual Program Review
 - 6.1.10. TAMUS Policy 15.99.07 Use of Vertebrate Animals
 - 6.1.11. TAMU Rule 15.99.07.M1 Use of Vertebrate Animals
- 6.2. References:
 - 6.2.1. ILAR News 1991; 33(4):68-70. The PHS Responds to Commonly Asked Questions.
 - 6.2.2. <u>Contemporary Topics 1997; 36(2):47-50.</u> FAQs about the PHS Policy on Humane Care and Use of Laboratory Animals.
 - 6.2.3. <u>CITI Program</u> (requires registration & log-in) Semiannual Evaluations in Depth (online training program)
 - 6.2.4. OLAW Webinar <u>Facility Inspections</u>
 - 6.2.5. OLAW 21st Century Cures Act Semiannual Facility Inspections
 - 6.2.6. AAALAC FAQ Frequency of program review and facility inspection
 - 6.2.7. AAALAC FAQ Managing and reporting adverse events
 - 6.2.8. AAALAC FAQ What are the reporting requirements for maintaining accreditation?
- 6.3. Additional Materials:



6.3.1. AWO: (requires TAMU NetID authentication)

- 6.3.1.1. TAMU-C-001 Inspection Checklist Vivarium Animal Housing & Procedures
- 6.3.1.2. TAMU-C-002 Inspection Checklist PI Locations
- 6.3.1.3. TAMU-C-003 Inspection Checklist Aquatic Animal Housing & Procedures
- 6.3.1.4. TAMU-C-004 Inspection Checklist Agriculture settings
- 6.3.1.5. TAMU-G-016 Guidelines for Transporting Animals on the Texas A&M Campus
- 6.3.1.6. TAMU-G-024 Guidelines for the Use of Expired Medical Materials
- 6.3.1.7. TAMU-S-006 Composition, Appointment, Responsibilities, and Training of the IACUC
- 6.3.1.8. TAMU-S-011 Semi-Annual Review Programmatic Review
- 6.3.1.9. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance
- 6.3.1.10. TAMU-S-013 Investigation of Potential Noncompliance
- 6.3.1.11. TAMU-S-016 Initial Inspection of New Animal Facilities and Study Areas
- 6.3.1.12. AWO-C-019 Inspection Self Evaluation PI Labs
- 6.3.1.13. AWO-C-020 Inspection Self Evaluation Agriculture settings

7. HISTORY

Effective Date	Version #	Description		
12/01/2020	000	College Station/Galveston: New format and content; replaced AWO-401		
02/01/2021	001	Houston/Kingsville: New document		
02/23/2021	002	Dallas: New document		
03/24/2022	003	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston		
10/20/2022	004	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.		
02/01/2023	005	College Station/Dallas/Galveston/Kingsville: Clarification of scope, updated definitions, inclusion of flexibilities per OLAW NOT-OD-21-164, addition of timely reporting of significant findings for rolling inspections, clarification of vehicle inspection/oversight, expansion of satellite facility inspection to include field locations for USDA regulated wildlife, expansion of references. Reviewed and approved via email.		
03/01/2023	006	Houston: Clarification of scope, updated definitions, inclusion of flexibilities per OLAW NOT-OD-21-164, addition of timely reporting of significant findings for rolling inspections, clarification of vehicle inspection/oversight, expansion of satellite facility inspection to include field locations for USDA regulated wildlife, expansion of references. Reviewed and approved via email.		
09/01/2024	007	College Station/Dallas/Galveston/Kingsville: Renewal; updated definition and references sections; updated procedure section to match OLAW Notice NOT-OD-24-076 related to inspection of USDA regulated facilities		
		NOTE: items above in red have only been approved by the College Station/Dallas/ Galveston/Kingsville IACUC.		