New York State Laboratory Animal Welfare Program Inspection Tool

Pre-inspection procedures

Laboratory Animal Welfare Program (LAWP) inspections are generally unannounced. However, the program does notify institutions 2–4-weeks in advance of an upcoming on-site inspection. This notice allows the LAWP, at its discretion, to request documents from the Institutional Animal Care and Use Committee (IACUC) ahead of inspections. Providing a general inspection window also affords institutions the opportunity to inform us of any days that may be unsuitable for inspections during this advance notice period. While the LAWP cannot guarantee that on-site inspections will not be conducted on these days, the program will certainly take them into consideration. It should also be noted that the LAWP reserves the right to periodically conduct entirely unannounced on-site inspections at its discretion. If the LAWP is performing an on-site inspection in response to a complaint, staff from the Wadsworth Center's Laboratory Investigative Unit may participate in the inspection along with LAWP staff.

The facility's certificate holder, Attending Veterinarian (AV), and contact person will be emailed advanced notice of the upcoming inspection 2-4 weeks prior to the inspection date. At this time the LAWP may also request a copy of their two most recent Institutional Animal Care and Use Committee (IACUC) meeting minutes. The minutes can be emailed directly to the LAWP or a file sharing service can be used (e.g., box.com, dropbox.com, Microsoft Teams, Google drive). When using a file sharing service, the documents will not be in our possession but will rather remain on a server owned or operated by your institution. To facilitate on-site inspections, the LAWP may also ask the facility to provide additional contact numbers, advise security of the upcoming inspection, and ensure that a vivarium staff member of suitable authority be available for the inspection.

Please also note that in addition to IACUC meeting minutes, the LAWP may also request to review Standard Operating Procedures (SOPs), IACUC protocols and/or other documents to ensure compliance with 10 NYCRR 55-1. Such requests may be prior to, during or after the on-site inspection.

Finally, between receipt of your initial notification and the time of your facility's inspection, please prepare a list of all approved Principal Investigator labs in which procedures on living animals may be performed outside of the vivarium. The LAWP may request to review this information upon arrival at your institution and may also elect to inspect one or more of these areas. Given this, you may wish to advise such investigators of the upcoming inspection and remind them and their staff that they must facilitate any LAWP inspections of laboratory space involving the use of living animals.

Facility Inspection

In addition to the 2–4-week notice mentioned above, the LAWP also advises institutions of the inspector's anticipated arrival time 2-24 hours before an inspection. Such notice maybe given by phone and/or email to the facility's certificate holder, AV, and/or contact person. At the start of an inspection, a brief entrance conference will be conducted. The goal of the entrance conference is to determine the inspection plan, including the number and type of rooms/buildings (i.e., quarantine, ABSL-2 and/or -3, species housed, etc.) to be inspected as well as the room order.

Inspections will be conducted using the table below which outlines requirements that need to be met. Certificate holders should use this table as a tool to help prepare for an inspection. References used to develop this table include: 10 NYCRR Subpart 55-1, the latest edition of The Guide for the Care and Use of Laboratory Animals (The Guide), the latest edition of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, and applicable National Institute of Health (NIH) Office of Laboratory Animal Welfare (OLAW) guidance and notices.

Facilities not housing animals when an inspection is being planned will not be inspected so long as they have not housed animals in the preceding 6 months and that there are no plans to house animals in the upcoming 6 months.

REQUIREMENT	GUIDANCE	REGULATORY AND OTHER RELEVANT REFERENCES
General Facility Conditions		
The animal care and use program implements adequate* veterinary care.	• If a full-time veterinarian is not available on site, a consulting or part-time veterinarian should be available in visits at intervals appropriate* to programmatic needs. In such instances, there must be an individual with assigned responsibility for daily animal care and use and facility management. • The AV should be familiar with the species and various uses of animals in the institutional research, teaching, testing, or production programs and have access to medical and experimental treatment records. • SOPs and/or observations indicate that animal health concerns are communicated to the AV or appropriate* designee in an accurate and timely manner. • SOPs indicate that emergency veterinary care is available 24/7/365. A veterinarian or appropriate designee must be available to expeditiously assess the animal's condition, treat the animal, investigate an unexpected death, or advise on euthanasia.	55-1.4(b) and 55-1.5(a) The Guide pg. 14, 105-106 and 112-115
Animal quarters are kept clean and contain adequate bedding and/or structures for resting.	• SOPs and/or observations indicate that soiled bedding is removed and replaced with fresh materials as often as necessary to keep animals clean and dry. • SOPs and/or observations indicate that enclosures and accessories, such as tops, are sanitized at least once every 2 weeks and solid-bottom caging, bottles, and sipper tubes are sanitized at least once a week. Some types of cages and housing systems may require less frequent	55-1.5(a) and 55-1.6 The Guide pg. 56, 69-71 and 82

	cleaning or disinfection; such housing may include large cages with very low animal density and frequent bedding changes, cages containing animals in gnotobiotic conditions with frequent bedding changes, individually ventilated cages, and cages used for special situations. Other circumstances, such as filter-topped cages without forced-air ventilation, animals that urinate excessively, or densely populated enclosures, may require more frequent sanitation. • SOPs and/or observations indicate that pen/runs are flushed at least once a day. During flushing, animals should be kept dry. • SOPs and/or observations indicate acceptable* primary enclosures for aquatic species allow for the observation of the animals with minimal disturbance.	
Animal quarters are of suitable size.	• Observations indicate that animal quarters are suitable in size for the species and number of animals housed such that at a minimum, animals must have enough space to express their natural postures and postural adjustments without touching the enclosure walls or ceiling, be able to turn around, and have ready access to food and water. In addition, there must be sufficient space to comfortably rest away from areas soiled by urine and feces. • Departures from Guide "must" statements are only permissible with IACUC-approved scientific justification and/or for IACUC-approved veterinary or animal welfare reasons. Refer to OLAW's Departure from Guide: Report Requirements Departure Flowchart	55-1.5(a) and 55-1.6 The Guide pg.55-63
Animals are monitored at least once a day.	• Records indicate that animals are observed for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs. Such observation should occur at least daily, but more frequent observations may be required, such as during postoperative recovery, when animals are ill or have a physical deficit, or when animals are approaching a study endpoint. • Records of daily monitoring should be available in animal housing rooms for ease of inspection by facility veterinary and compliance staff. These records should be completed daily and contain the date, and initials of the person providing care.	55-1.1(a), 55-1.5(a) The Guide pg. 112-115
Animals are provided sufficient food and water.	• Records indicate that animals are fed palatable, uncontaminated diets that meet their nutritional and behavioral needs at least daily, or	55-1.5(a) and 55-1.6 The Guide pg. 65

	according to their particular requirements, unless the protocol in which they are being used requires otherwise.	
Medical records are accurate and up to date.	• Medical records are a key element of the veterinary care program and are considered critical for documenting animal well-being as well as tracking animal care and use at the facility. These records should be available for review upon request. • A veterinarian should be involved in establishing, reviewing, and overseeing medical and animal use records. • All those involved in animal care and use must comply with federal laws and regulations regarding veterinary drugs and treatments. • Drug records and storage procedures should be reviewed during facility inspections. • Records of daily monitoring should be available in animal housing rooms for ease of inspection by facility veterinary and compliance staff. These records should be completed daily and contain the date, description of treatment, and initials of the person providing care.	55-1.1(a) and 55-1.5(c) The Guide pg. 115
Careful consideration of the humane treatment of animals during a period of fluid and/or food restriction is conducted.	• Studies should use the least restriction necessary to achieve the scientific objective while maintaining animal wellbeing. • Animal protocols that involve the use of food or fluid regulation require the evaluation of three factors: the necessary level of regulation, potential adverse consequences of regulation, and methods for assessing the health and well-being of the animals. Documentation must be available upon request to demonstrate due consideration of these three factors. These documents may take the form of: IACUC meeting minutes, relevant protocol sections, pre-review emails, and/or related documents. • Records indicate that animals are monitored daily, and body weights are checked at least weekly and more often for animals requiring greater restrictions. • Written records should be maintained for each animal to document daily food and fluid consumption, hydration status, and any behavioral and clinical changes used as criteria for temporary or permanent removal of an animal from a protocol.	55-1.1(a), 55-1.5(a) and 55-1.6 The Guide pg. 30-31
Environmental enrichment is appropriate for the species.	• Enrichment programs should be reviewed by the IACUC, researchers, and veterinarian on a regular basis to ensure that they are beneficial to animal well-being and consistent with the goals of animal use. They	55-1.5(a) The Guide pg. 52-53

	should be updated as needed to ensure that they reflect current knowledge. • Observations indicate that species-appropriate enrichment is provided. Documentation must be available upon request to demonstrate any exceptions. These documents may take the form of: IACUC meeting minutes, relevant protocol sections, pre-review emails, and/or related documents.	
Food is stored properly.	• Observations indicate that food is stored up off the floor and is not exposed to extreme temperature/humidity fluctuations or wet conditions. • Observations indicate that any open bags are being stored in vermin-proof containers. • Food containers should be labeled with type of food and mill date/expiration date. • Records indicate that food containers are cleaned and sanitized regularly. • Observations indicate that specialized diets are being stored and handled according to manufacturer recommendations.	55-1.5(a) and 55-1.6 The Guide pg.65-67, 141-142
The air quality and ventilation in animal holding rooms is sufficient.	• Records indicate that all animal holding rooms have at least 10 air changes per hour.	55-1.5(a) and 55-1.6 The Guide pg. 46
Animal holding rooms are maintained at the appropriate temperature and humidity.	• Records indicate that temperature and humidity is being monitored in all animal rooms and ranges are acceptable for the species being housed.	55-1.5(a) and 55-1.6 The Guide pg. 43-45
Lighting in animal holding rooms is acceptable.	• Observations indicate that illumination is appropriate for the animals' well-being and for the provision of adequate animal care.	55-1.5(a) The Guide pg. 47-49
Noise and vibration are well-controlled in animal holding rooms.	• Observations indicate that noise control is considered in the facility design and operation. For example, animal areas are separate from human areas and noisy animals are housed away from quieter animals.	55-1.5(a) The Guide pg. 49-50
Personnel involved with the care and use of animals are adequately trained.	• SOPs and/or observations and/or records indicate that all personnel involved with the care and use of animals are adequately educated, trained, and/or qualified in basic principles of laboratory animal science to help ensure high-quality science and animal well-being. • The IACUC, together with the AV, is responsible for determining that personnel are appropriately qualified and trained in the procedures they are authorized to perform.	55-1.1(a), 55-1.2 and 55-1.5(a) The Guide pg. 15 and 115-116

Pest control measures are in place.	• Observations indicate a pest-free environment and/or evidence of pest-control measures. • Records indicate that pest control procedures are in place and if managed in-house, such as with live traps, that they are monitored daily.	55-1.5(a) The Guide pg. 74
A health monitoring program is enforced.	• SOPs and/or observations and/or records indicate that appropriate procedures are in place for disease surveillance and diagnosis.	55-1.5(a) The Guide pg. 112-113
Animal transportation is conducted appropriately.	• SOPs and/or observations and/or records indicate that careful planning for all types of transportation occurs to ensure animal safety and well-being. The process of transportation should provide an appropriate level of animal biosecurity (see definition on "GUIDE" page 109) while minimizing zoonotic risks, protecting against environmental extremes, avoiding overcrowding, providing for the animals' physical, physiologic, or behavioral needs and comfort, and protecting the animals and personnel from physical trauma. • SOPs and/or observations and/or records indicate that the movement of animals within or between sites or institutions is planned and coordinated by responsible and well-trained persons at the sending and receiving sites to minimize animal transit time or delays in receipt.	55-1.5(b) The Guide pg. 107-109
Procedure/Surgery Spaces		
The space to conduct surgery or perform other procedures is appropriate.	• Observations indicate that dedicated facilities or spaces are available within the vivarium for aseptic surgery that ensure cleanliness and minimize unnecessary traffic. • Observations and records indicate that major surgical procedures on non-rodents are conducted only in facilities intended for that purpose which shall be maintained under aseptic conditions.	55-1.5(a) The Guide pg. 116-117 Animal Welfare Act and Animal Welfare Regulations pg. 59
Surgical training is adequate and well documented.	• Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced- that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns. • Surgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed, and timely corrective changes are instituted. Surgical records should be maintained and available for review.	55-1.1(a) and 55-1.2 The Guide pg. 115-116

	• Training records should include details such as time spent, name/description of procedures or techniques, and the training method (hands on, online module, etc.). • Observations and/or records indicate that the IACUC, together with the AV, is responsible for determining that personnel performing surgical procedures are appropriately qualified and trained in the procedures they are authorized to perform.	
Aseptic technique is being performed in all surgical procedures.	• General principles of aseptic technique should be followed for all survival surgical procedures. • SOPs, protocol review, and/or observations indicate the use of aseptic technique including preparation of the patient, such as hair or feather removal and disinfection of the operative site; preparation of the surgeon, such as the provision of appropriate surgical attire, face masks, and sterile surgical gloves; sterilization of instruments, supplies, and implanted materials; and the use of operative techniques to reduce the likelihood of infection. • SOPs and/or observations indicate that appropriate methods of sterilization are used, as distinct from disinfection.	55-1.1(a), 55-1.2, 55-1.4(b) The Guide pg. 116 and 118-119
Injections and blood collections are performed appropriately.	• SOPs, protocol review, and/or observations indicate that blood collections and injections are performed using aseptic technique by appropriately trained individuals. • SOPs and/or observations indicate that the volume of blood collected at a given time is appropriate for the species, animal's size, and vessel used. • SOPs and/or observations indicate that the volume of an injection is appropriate for the species, animal's size, and injection site.	55-1.2, 55-1.4(b), 55-1.5(a)
Anesthetics and analgesics are used appropriately.	• Protocol review indicates that the selection of analgesics and anesthetics was determined by what best meets clinical and humane requirements as well as the needs of the research protocol. Additionally, the selection of analgesics and anesthetics provides maximum comfort, unless it defeats the purpose of the experiment. • Exceptions for the provision of maximum comfort for the appropriate use of anesthetics and analgesics can be proposed after receiving recommendations from the person in charge of animal care. Exceptions can be approved by the IACUC during protocol review, so long as sufficient scientific justification is provided. Such recommendations and justification should be documented in the approved protocol(s), IACUC	55-1.5(c) The Guide pg. 121-123

	meeting minutes, and or pre-review materials and available for LAWP inspection upon request. • SOPs and/or observations and/or records indicate that animals are closely monitored during and after painful procedures and receive additional drugs, as needed, to ensure appropriate analgesic management. Records of anesthetic and analgesic administration should be maintained and available for inspection. • Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely.	
All anesthetics, analgesics, and other drugs are stored and labeled appropriately.	• The LAWP expects all drugs to be labeled with the drug name, concentration, and expiration date. Additionally, the LAWP expects all drugs to be used before their expiration dates and be acquired, stored, recorded, and disposed of legally and safely.	55-1.1(a) for drugs other than anesthetics and analgesics and 55-1.5(c) for anesthetics and analgesics The Guide pg. 122
Intraoperative monitoring and post-operative care of animals is adequate.	• SOPs and/or observations indicate that careful monitoring of animals under anesthesia is being conducted and that timely attention is paid to problems in the perioperative period. • Monitoring includes routine evaluation of anesthetic depth and physiologic functions and conditions, such as body temperature, cardiac and respiratory rates and pattern, and blood pressure, and should be appropriately documented. • SOPs and/or observations indicate that post-operative animals are housed in a clean, dry, and comfortable area where they can be observed frequently by trained personnel. Records of post-operative care should be maintained and available for inspection. These records should be completed daily and contain the date, description, and initials of the person providing post-operative care.	55-1.1(a), 55-1.2, and 55-1.4(b) The Guide pg. 115-120
Euthanasia		
The euthanasia methods used are appropriate.	• SOPs are easily accessible to personnel and describe the method(s) of euthanasia. • Records indicate that all personnel performing euthanasia have been adequately trained. • It is essential that euthanasia be performed by personnel skilled in methods for the species in question and in a professional and	55-1.5(d-f) The Guide pg. 123-124 AVMA Guidelines for the Euthanasia of Animals

	compassionate manner. Special attention is required to ensure proficiency when a physical method and/or method that is conditionally approved by the AVMA is used. • SOPs and/or observations indicate that death is confirmed by personnel trained to recognize cessation of vital signs in the species being euthanized. • All methods of euthanasia should be reviewed and approved by the veterinarian and IACUC. Additionally, methods of euthanasia should be clearly described in approved protocols. • SOPs and/or observations and/or protocol review indicate that euthanasia methods are consistent with the most current version of the *AVMA Guidelines for the Euthanasia of Animals.* Any deviations should be clearly described in the approved protocol(s) and justified for scientific or medical reasons. • Records indicate that any deviation is justified for scientific or medical reasons, euthanasia methods should be consistent with the most current version of the *AVMA Guidelines for the Euthanasia of Animals*.	
Protocol Related Document Review		
When using non-pharmaceutical-grade chemicals or substances, their use should be approved by the IACUC.	• Observations and/or protocol review indicate that pharmaceutical-grade chemicals or substances are used. • The use of pharmaceutical-grade chemicals and other substances ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. They should therefore be used, when available, for all animal-related procedures. • The use of non-pharmaceutical-grade chemicals or substances may be necessary to meet the scientific goals of a project or when a pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues related to its use. These considerations should be documented in the approved protocol(s), IACUC meeting minutes, and or pre-review materials.	55-1.1(a) and 55-1.4(b) The Guide pg. 31

Non-pharmaceutical-grade anesthetics and analgesics should only be used after receiving IACUC approval and a recommendation from the person in charge of animal care.	• Observations and/or protocol review indicate that pharmaceutical-grade anesthetics and analgesics are used. • The use of pharmaceutical-grade anesthetics and analgesics ensures that toxic or unwanted side effects are not introduced into studies conducted with experimental animals. Additionally, it ensures the provision of maximum comfort for the study subjects. They should therefore be used, when available, for all animal-related procedures. • The use of non-pharmaceutical-grade chemicals or substances as anesthetics and/or analgesics may be necessary to meet the scientific goals of a project or when a pharmaceutical-grade product is unavailable. In such instances, consideration should be given to the grade, purity, sterility, pH, pyrogenicity, osmolality, stability, site and route of administration, formulation, compatibility, and pharmacokinetics of the chemical or substance to be administered, as well as animal welfare and scientific issues related to its use. These considerations should be clearly described in the approved protocol(s).	55-1.1(a), 55-1.4(b), and 55-1.5(c) The Guide pg. 31
The IACUC reviews the propriety of the procedures used.	• Protocol review and/or IACUC meeting minutes indicate that the IACUC committee members evaluate scientific elements of protocols as they relate to the welfare and use of the animals. • The animal use protocol is a detailed description of the proposed use of laboratory animals. The following topics should be considered in the preparation of the protocol by the researcher and its review by the IACUC: 1. Rationale and purpose of the proposed use of animals. 2. A clear and concise sequential description of the procedures involving the use of animals that is easily understood by all members of the committee. 3. Availability or appropriateness of the use of less invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (see Appendix A, Alternatives). 4. Justification of the species and number of animals proposed; whenever possible, the number of animals and experimental group sizes should be statistically justified (e.g., provision of a power analysis; see Appendix A, Experimental Design and Statistics). 5. Unnecessary duplication of experiments. 6. Nonstandard housing and husbandry requirements.	55-1.1(b) and 55-1.4(b) The Guide pg. 25-26

	7. Impact of the proposed procedures on the animals' well-being. 8. Appropriate sedation, analgesia, and anesthesia (indices of pain or invasiveness might aid in the preparation and review of protocols; see Appendix A, Anesthesia, Pain, and Surgery). 9. Conduct of surgical procedures, including multiple operative procedures. 10. Postprocedural care and observation (e.g., inclusion of post-treatment or postsurgical animal assessment forms). 11. Description and rationale for anticipated or selected endpoints. 12. Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated. 13. Method of euthanasia or disposition of animals, including planning for care of long-lived species after study completion. 14. Adequacy of training and experience of personnel in the procedures used, and roles and responsibilities of the personnel involved. 15. Use of hazardous materials and provision of a safe working environment.	
Laboratories and institutions must adhere to methods, techniques and experimental design as described in IACUC approved protocols.	• Observations and/or protocol review indicate that IACUC approved protocols and SOPs are adhered to.	55-1.1(a), 55-1.4(b) and, OLAW Notice # NOT-OD-05-034
Endpoint criteria is relevant, reliable, and being followed.	• Protocol review demonstrates endpoint criteria that is both humane and scientifically sound. Determination of humane endpoints should involve the PI, the veterinarian, and the IACUC. • Implementation of clear, appropriate, and humane experimental endpoints for animals, combined with close observation during invasive periods of experimentation, will assist in minimizing distress experienced by animals used in research, teaching, testing, and production. • Criteria for euthanasia include protocol-specific endpoints that will enable a prompt decision by the veterinarian and the investigator to ensure that the endpoint is humane and, whenever possible, the scientific objective of the protocol is achieved. • Unexpected deaths and signs of illness, distress, or other deviations from normal in animals should be reported promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary medical care.	The Guide pg. 27-28, 112 and 121-123

*** It should be noted that the use of the terms *adequate, appropriate, and acceptable* which are found throughout this inspection tool are subject to approval from the IACUC and require evidence that deliberation was given to these matters. The LAWP may request such evidence during the inspection process.**

Post-inspection procedures

At the end of the on-site inspection, a brief exit interview will be conducted immediately after the on-site inspection concludes. The goal of the exit interview is to provide the facility with the LAWP's preliminary findings. Items discussed during an inspection and its associated exit interview are considered to be preliminary findings and may be subject to change. If key personnel are not immediately available for an in-person exit interview, there is an option of a 30-minute conference call within 3 business days after the inspection.

The facility's SOP's, IACUC protocols and/or other documents may be requested at the exit interview or after the inspection. The LAWP will then issue a written report to the facility's Certificate Holder, AV, and Contact Person.

- If no deficiencies were issued, the report will state "no deficiencies issued". The facility's Certificate Holder, AV, or Contact Person must sign and date where it says, "Copy received by" and return it to the LAWP inspector.
- If no deficiencies were issued but the inspectors have recommendations that can be used by the facility to improve their practices, the report will state "no deficiencies issued" and will include Inspector Recommendations. The facility's Certificate Holder, AV, or Contact Person must sign and date where it says, "Copy received by" and return it to the LAWP inspector.
- If deficiencies were issued, the report will list each requirement, and the evidence found that the requirement was not met. For each deficiency issued you will need to provide a plan of correction. You have 10 business days to provide a plan of correction. Additional information on preparing a plan of correction is provided below. The facility's Certificate Holder, AV, or Contact Person must sign and date the report where it says, "Copy received by" and return it to the LAWP inspector.

Guidance for completion of the Plan of Correction (POC)

The plan of correction needs to include a root cause analysis and a description of the corrective action. Failure to include these items will result in an unacceptable POC and the facility will be required to resubmit the POC.

- Root Cause Analysis: the root cause analysis is a team process to identify the cause of a problem that resulted in the deficiency. This process is a chance to determine:
    - What problem was identified?
    - Why did the problem occur?
    - How did it occur?

    - When did it begin to occur?
    - Who was involved?
- Description of the Corrective Action: the corrective action describes the steps that were taken, or will be taken, to correct the problem that was identified. In addition, the corrective action needs to describe the time frame for completing the corrective action and what changes were made to policies, procedures or processes to ensure there will not be a repeat of the deficiency.

Contact Information

If you have any questions pertaining to your on-site inspection or this guidance, please contact the LAWP by email at AWP@health.ny.gov.