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 shall facilitate any LAWP inspections of laboratory space involving the use of living animals.

Facility Inspection

In addition to the 2-4 weeks' 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 there are no plans to house animals in the upcoming 6 months.

REQUIREMENT	GUIDANCE	REGULATORY REFERENCE
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 needs to be available in visits at intervals appropriate* to programmatic needs. In such instances, there shall be an individual with assigned responsibility for daily animal care and use and facility management. • The AV needs to 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 shall be available to expeditiously assess the animal's condition, treat the animal, investigate an unexpected death, or advise on euthanasia.	55-1.4(a), 55-1.4(b) and 55-1.5(a)
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 cleaning or disinfection; such	55-1.5(a) and 55-1.6

	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 pens/runs are flushed at least once a day. During flushing, animals need to 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 shall 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 shall be sufficient space to comfortably rest away from areas soiled by urine and feces.	55-1.5(a) and 55-1.6
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 needs to 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 shall be available upon request	55-1.1(a), 55-1.5(a)
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 according to their requirements, unless the protocol in which they are being used requires otherwise.	55-1.5(a) and 55-1.6
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 shall be available for review upon request. • A veterinarian shall be involved in establishing, reviewing, and overseeing medical and animal use records.	55-1.1(a) and 55-1.5(c)

	• All those involved in animal care and use shall comply with federal laws and regulations regarding veterinary drugs and treatments. • Drug records and storage procedures need to be reviewed during facility inspections.	
Careful consideration of the humane treatment of animals during a period of fluid and/or food restriction is conducted.	• Studies shall 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 shall 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 shall 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
Environmental enrichment is appropriate for the species.	• Enrichment programs need to be reviewed by the IACUC, researchers, and a veterinarian on a regular basis to ensure that they are beneficial to animal well-being and consistent with the goals of animal use. They need to be updated as needed to ensure that they reflect current knowledge. • Observations indicate that species-appropriate enrichment is provided. Documentation shall 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.	55-1.5(a)
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.	55-1.5(a) and 55-1.6

	• Food containers need to 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.	
The air quality and ventilation in animal holding rooms is sufficient.	• Records and/or observations indicate that all animal holding rooms have sufficient air quality and adequate ventilation.	55-1.5(a) and 55-1.6
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
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)
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)
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)
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)
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)
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	55-1.5(b)

	process of transportation needs to 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.	
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)
Surgical training is adequate and well documented.	• Researchers conducting surgical procedures shall have appropriate training to ensure that good surgical technique is practiced. • Surgical outcomes need to be continually and thoroughly assessed to ensure that appropriate procedures are followed. • Surgical records shall be maintained and available for review. • Training records shall be maintained and available for review. • 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.	55-1.1(a) and 55-1.2
Aseptic technique is being performed for surgical procedures.	• General principles of aseptic technique need to be followed for survival surgical procedures. • SOPs, protocol review, and/or observations indicate the use of aseptic technique.	55-1.1(a), 55-1.2, 55-1.4(b)
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.	55-1.2, 55-1.4(b), 55-1.5(a)

	• 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.	
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 shall be documented in the approved protocol(s), IACUC 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 analgesic administration shall be maintained and available for inspection. • Agents that provide anesthesia and analgesia shall be used before their expiration dates and need to be acquired, stored, their use recorded, and disposed of legally and safely.	55-1.5(c)
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
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	55-1.1(a), 55-1.2, and 55-1.4(b)

	rates and pattern, and blood pressure, and need to 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 shall be maintained and available for inspection.	
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 compassionate manner. • Evaluation of euthanasia may include direct observation and/or review of training records, especially when "physical method's" and/or methods that are "acceptable with conditions" as described by the AVMA are 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 shall be reviewed and approved by the veterinarian and IACUC. Additionally, methods of euthanasia shall 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 shall be clearly described in the approved protocol(s) and justified for scientific or medical reasons.	55-1.5(d-f)
Protocol Related Document Review		
When using nonpharmaceutical grade chemicals or substances, their use shall 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 therefore need to be used, when available, for all animal related procedures.	55-1.1(a) and 55-1.4(b)

	• The use of nonpharmaceutical 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 needs to 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 need to be documented in the approved protocol(s), IACUC meeting minutes, and or pre-review materials.	
Nonpharmaceutical grade anesthetics and analgesics shall 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 shall therefore be used, when available, for all animal related procedures. • The use of nonpharmaceutical 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 needs to 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 need to be clearly described in the approved protocol(s).	55-1.1(a), 55-1.4(b), and 55-1.5(c)
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 need to 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.	55-1.1(b) and 55-1.4(b)

	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 needs to 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. 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 shall 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)

Endpoint criteria are relevant, reliable, and being followed.	• Protocol review demonstrates endpoint criteria that is both humane and scientifically sound. Determination of humane endpoints shall 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 need to be reported promptly and investigated, as necessary, to ensure appropriate and timely delivery of veterinary medical care.	55-1.1(a), 55-1.4(b)

*** 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 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 shall 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 shall 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 shall 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, or by phone at (518) 474-2942.