

Comment	LAWP Response
<p>Some certificate holders are concerned about the use of The Guide for the Care and Use of Laboratory Animals, 8th edition (referred to as the <i>Guide</i>) in assessing animal research programs regulated by the Laboratory Animal Welfare Program (LAWP).</p> <p>Specifically, some certificate holders are concerned that reliance on the provisions and standards in the Guide as a basis of enforcement and penalties without additional rulemaking under New York State law is inappropriate and represents a significant expansion of the NYSDOH regulatory authority.</p>	<p>10 NYCRR 55-1.6 gives the LAWP authority to use the <i>Guide</i> as a guide for adequate sanitation, ventilation, food, temperature and space.</p> <p>The LAWP also refers to the <i>Guide</i>, along with other widely accepted sources, to assess aspects of animal care not explicitly mentioned in 10 NYCRR 55-1.6. In this instance the program uses the <i>Guide</i> as a source of expert opinion to guide the interpretation of sections 55-1.1 to 55-1.5 of 10 NYCRR Subpart 55-1.</p> <p>As noted in the introduction to the Tool, the LAWP uses published expert opinions, consensus statements, professional judgement of subject matter experts, and other sources of information to apply the broad requirements described in 10 NYCRR Subpart 55-1. This allows LAWP practices to evolve with the field and to be flexible in applying the requirements to situations which require the professional judgement of the AV and/or IACUC.</p>
<p>A few certificate holders are opposed to the LAWP reviewing decisions and deliberations made by the IACUC. These institutions are concerned that the review is too wide-reaching and could be detrimental to the independence of this institutional regulating body.</p>	<p>10 NYCRR 55-1.4(b) states that “the laboratory or institution shall have an animal care committee which shall review the propriety of procedures used and the scientific justification for the use of animals in experiments, tests, and investigations, including educational demonstrations.” To determine if regulated institutions meet these requirements, the LAWP must review applicable records, documentation, and other information. Such reviews include minutes and other materials generated from IACUC deliberations. The purpose of these reviews is to confirm that observations during an inspection have been approved by the IACUC in accordance with 10 NYCRR 55-1.4(b) as well as 55-1.1(a), 55-1.1(b), 1.5(c), and 55-1.5(d-f).</p>

<p>Some certificate holders requested clarification on which species the LAWP has oversight of. These institutions are concerned that the LAWP's oversight of species beyond living mammals and birds, such as poikilotherms, expands the scope of 10 NYCRR Subpart 55-1.</p>	<p>10 NYCRR 55-1.1(a) states that "Approval may be granted laboratories and institutions for the use of the living animals in properly performed or conducted scientific tests, experiments, or investigations, including educational demonstrations. Living animals include living mammals and birds."</p> <p>The LAWP maintains that the word "include" in the regulation does not exclude other species. "Include" or similar language is commonly used in the Department's regulatory requirements to give examples of the scope of a requirement.</p>
<p>Some certificate holders are concerned about the LAWP's requirements for record keeping. These institutions claim that the requirements are too specific, lack flexibility, and create additional burdens beyond what is required by the <i>Guide</i>.</p> <p>Additionally, some certificate holders believe that the perceived increase in requirements around inspections and recordkeeping should go through rulemaking to examine the burden on certificate holders.</p>	<p>The LAWP must review applicable records, documentation, and other information to assess compliance with requirements, including 10 NYCRR 55-1.2, 55-1.5(a), and 55-1.5(c). Records must be available upon request.</p> <p>Rather than requiring specific formatting and details to include in records, <b>the language in the Inspection Tool has been revised</b> to indicate that records shall be maintained and made available for review upon request.</p> <p>This is guidance that is intended to clarify requirements and assist regulated parties in meeting the requirements.</p>
<p>Some certificate holders are concerned about the LAWP's requirements for aseptic technique. These institutions claim that the degree to which aseptic conditions are maintained is overly prescriptive and not always appropriate based on the species or setting. They state that donning of surgical attire, face masks, and sterile gloves is not required by the <i>Guide</i> for use in rodents.</p>	<p>Aseptic technique helps ensure animal health/welfare as well as data quality. That said, <b>the Inspection Tool has been modified</b> to account for the fact that species and setting may impact specific details.</p>

<p>After the conclusion of a facility inspection, the LAWP immediately holds an “exit interview” to discuss the inspector’s preliminary findings. A few certificate holders had concerns over the timing of the exit interview and have requested that the start of the meeting be delayed so that key personnel, including legal representation, can attend the meeting.</p>	<p>It is not possible to schedule inspection timelines around the availability of specific facility personnel.</p> <p>If all key personnel are not available for the exit interview at the conclusion of an on-site inspection, the LAWP will offer a 30-minute conference call within 24 to 48 hours of the close of the inspection (not including weekends). This would be the one and only exit interview.</p>
<p>Some certificate holders requested that there be guidance given on the institution’s ability to have institutional counsel present for the inspection and the ability to request that inspectors wait a reasonable amount of time to have counsel join before proceeding with the inspection.</p>	<p>Facilities can have any personnel they wish present for an inspection. However, it is not possible to schedule inspection timelines around the availability of specific personnel. The LAWP will advise facilities of their anticipated arrival 2-24 hours in advance of an inspection and any personnel wishing to join the inspection should be notified at that time by the facility.</p>
<p>A few certificate holders have requested that LAWP hold a “final” interview (in addition to the exit interview) before their conclusions, including deficiencies, are documented in the final inspection report.</p>	<p>The LAWP does not hold meetings to discuss their final assessment of regulated institutions.</p>
<p>A few certificate holders have requested that the LAWP develop a process that would allow institutions to appeal deficiencies.</p>	<p>The LAWP does not have a formal appeals process. However, as indicated in the tool, a brief exit interview will be conducted at the completion of the on-site inspection, providing an opportunity to discuss adverse findings. These findings will be considered preliminary and may be subject to change upon information provided during or after the exit interview.</p>
<p>One certificate holder requested clarification on how far in advance the LAWP notifies certificate holders on its anticipated arrival</p>	<p>The LAWP will advise institutions of an upcoming inspection 2-24 hours before arrival.</p>

for an inspection and stated that a 12–24-hour warning would be preferable	
Some certificate holders expressed concerns related to the terms “Standard Operating Procedures (SOPs)” and “Root Cause Analysis.” Specifically, it was noted that these terms could have several meanings, especially in a regulatory environment, as well as add additional burden.	<p>The term “Standard Operating Procedures” is widely used and does not exclude other documents that outline standard processes and procedures.</p> <p>The term “root cause analysis” was selected and described in the Inspection Tool to assist facilities in developing an appropriate plan of correction (POC). The intent is not to add burden but rather provide facilities with clear instructions on how to write a POC.</p>
<p>Some certificate holders expressed concerns about the lack of guidance in how facilities that are regulated by other entities, including the federal government, are to comply with the New York State regulations.</p> <p>Additionally, a concern was raised about applying New York State regulations, which are substantially similar to federal regulations, to certificate holders that are not subject to federal regulations.</p>	The purpose of the Inspection Tool is to provide facilities with guidance on how to comply with the New York State requirements. Facilities that are also regulated by other entities, such as the USDA and OLAW, should be following those associated requirements as well. Those facilities which are not subject to federal requirements must meet the state requirements whether they are similar to the federal requirement or not.
Some certificate holders expressed concerns about the protection of staff identities from the Freedom of Information Law and the Freedom of Information Act.	Please contact the New York State Department of Health Records Access Office with any questions related to the Freedom of Information Law and the Freedom the Information Act.
<p>Some certificate holders inferred that the LAWP was elevating Guide “should” statements to “must” statements.</p> <p>The examples provided included a) the Inspection Tool requires animal body weights to be checked weekly whereas the Guide describes a minimum of weekly recording of</p>	<p><b>The Tool has been updated to remove the word “must”.</b> The word “must” has been replaced with the word “shall” and this indicates a NYS LAWP regulatory requirement.</p> <p><b>The word “should” has been replaced with the phrases “need to” or “needs to”.</b> The</p>

<p>body weights for food and water regulated animals and b) The Inspection Tool requires the air quality systems to perform at least 10 changes per hour, whereas the Guide has a 10-15 change per hour recommendation.</p>	<p>LAWP intends for these phrases to indicate regulatory guidance rather than an explicit regulatory requirement per se.</p> <p>It should be noted that the Inspection Tool's references to "at least weekly" body weight checks is comparable to the Guide language.</p> <p><b>Reference to specific air changes per hour has been removed from the Inspection Tool.</b></p>
<p>Some certificate holders questioned whether the euthanasia section of the Inspection Tool is in reference to the New York State requirement that dogs and cats used in research be adopted out if deemed suitable once a protocol is completed.</p>	<p>This section of the Inspection Tool is <b>not</b> referring to the New York State Education requirement that dogs and cats used in research be adopted.</p>
<p>One certificate holder had two questions related to the following statement (found in the Euthanasia section of the Inspection Tool): "<b>Special attention</b> is required to ensure proficiency when a physical method and/or <b>method that is conditionally approved by the AVMA</b> is used."</p> <p>The first question was a request for more guidance on what is meant by "special attention" and how will the LAWPs evaluate this?</p> <p>The second question was requesting clarification on if the words "acceptable with conditions" (AVMA language) were replaced with "conditionally approved" (as written in the Inspection Tool).</p>	<p><b>The LAWPs understand the need for clarity on this point and has revised the Inspection Tool accordingly.</b></p>