

## **Technical Report**

Illumination Control Overview for Vivaria

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Lutron Electronics Co., Inc.  
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# Technical Report

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## Illumination Control Overview for Vivaria

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## Illumination Control Overview for Vivaria

### **Abstract**

Vivaria often represent a small, but comparatively complex, piece of a larger project. Lighting requirements in vivaria spaces are frequently very different from typical occupied spaces. Activities in these areas pose unique challenges, and specifiers without subject matter expertise may jeopardize project success with unclear or undiscerning specifications.

In this whitepaper we will

- Define “vivarium” and discuss their unique lighting requirements
- Present and discuss specific questions to ask when preparing a lighting specification
- Identify lighting system designs that minimize risk and ensure reliability and functionality within the facility
- Review regulatory requirements and illumination recommendations

The goal of this whitepaper is to help experienced lighting design professionals understand the design requirements associated with vivaria and specify an appropriate lighting control system with confidence.

### **Executive Summary**

Illumination guidelines for Vivaria have been established by various organizations including the National Institutes of Health (NIH), the Institute for Animal Laboratory Research (ILAR), and the Canadian Council on Animal Care (CCAC). In addition, although the FDA does not specifically regulate lighting control in vivaria, the presence of appropriate lighting control systems enhances facility integrity, and is therefore a factor in achieving a positive judgment by the FDA.

By asking the right questions at the beginning of the design process, and working with a lighting control manufacturer who can offer both the lighting control solutions and the in-depth knowledge of vivarium control, specifiers will be able to identify the right combination of required lighting control strategies including one or more of the following:

- Operator control stations
- Building Management System integration
- Environmental Monitoring System integration
- Dimming performance
- Time clock functions
- Automation overrides
- Individual lamp control
- Light level monitoring
- Alarms
- Historical data retention
- Shade control

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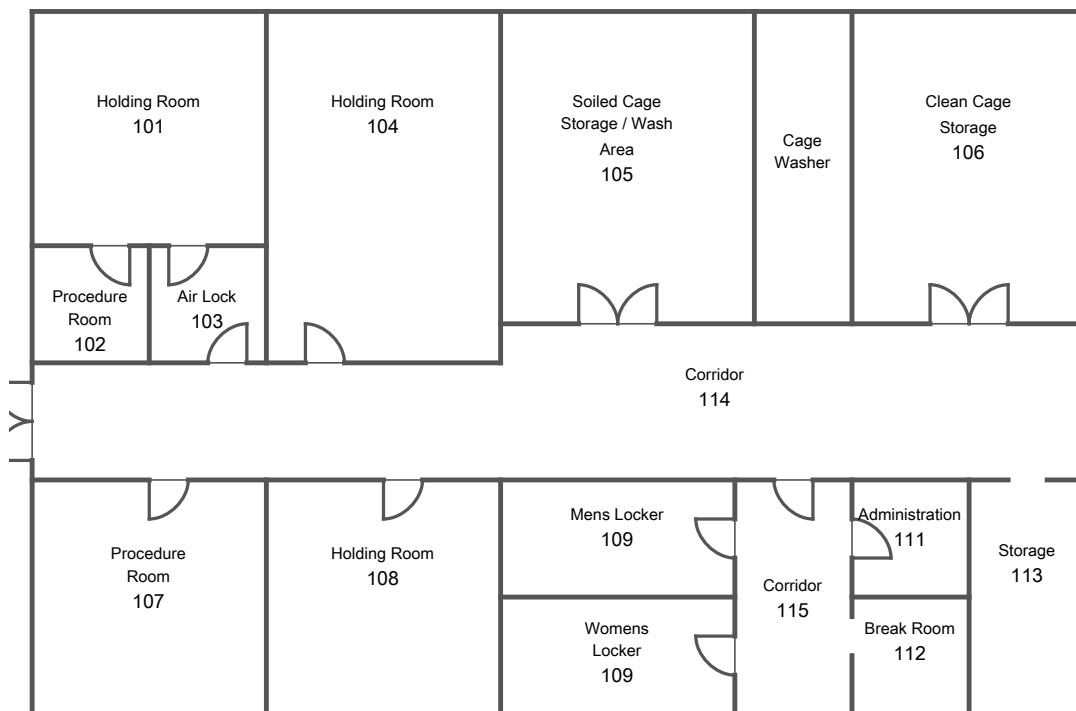
## Illumination Control Overview for Vivaria

### What is a Vivarium?

A vivarium is a place, such as a research laboratory, zoo, terrarium, or farm, where live animals or plants are kept under controlled conditions, often simulating the natural environment.

In a vivarium, a portion of the ecosystem for a particular species is simulated on a smaller scale, with controls for environmental conditions. This whitepaper primarily focuses on the type of animal facilities typically found in medical research, pharmaceutical companies, and universities.

A typical vivarium is made up of animal holding rooms, procedure rooms, cage wash areas, feed storage rooms, and bedding storage rooms. Lighting control is most critical in sensitive areas: animal holding rooms, procedure rooms, and other spaces where deviation from expected environmental settings could invalidate research or otherwise cause animal disruption.



Most vivaria are small sections within a building, usually confined to a single floor or less. It is unlikely the complex environmental controls requirements of the vivarium space are similar to those of the rest of the building. A building's primary environmental controls are usually the responsibility of the building's facility group, in contrast the day- to- day control of the vivarium's environment is the usually the responsibility of the research team.

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## Illumination Control Overview for Vivaria

Lighting manufacturers frequently provide design guidance to specifiers and contractors to aid implementation of control narratives. Many professionals who are familiar with lighting control requirements for most types of buildings have little or no experience with lighting design and control requirements for vivaria. There are risks in applying traditional commercial lighting control design to vivaria. Improper specification can lead a system that cannot comply with the research team's needs. Rectifying specification issues can result in significant additional costs from additional components, labor, and/or programming, as well as delays in project completion.

In worst case scenarios improper specification can lead to loss of or disqualification of research. If the cause of the loss can be attributed to failures of the specification and construction teams they may be pursued for financial damages. It is critical to work with a lighting controls manufacturer with experience in vivarium systems and the ability to propose and implement complementary solutions.

This whitepaper and the **Vivarium Specification Guide** contain design considerations and best practices that contribute to an informed dialogue. They can be used to achieve an appropriate lighting specification, reduce risk of callbacks and revisions, and ultimately avoid lighting systems that do not adequately support scientific discovery.

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### **Design Considerations**

No two vivaria are exactly alike. Unique research demands unique lighting and control protocols. The considerations below will help to frame up the right specification, ensure that critical issues have been addressed, and reduce additional costs due to change orders and rework.

### **Essential Design Considerations**

Essential design considerations are foundational choices made by the design team that profoundly effect the systems capabilities and reliability.

#### **1. Vivaria systems require subject matter expertise and experience to successfully implement.**

Many lighting controls manufacturers produce reliable and robust equipment. While many systems can meet the technical prerequisites of the specification, few manufacturers have significant experience in the field of vivarium.

*System considerations — Complexities innate to vivarium are rarely found elsewhere. Combining them with live animals creates high risk scenarios. Choosing a reputable manufacturer with a history of vivarium project successes will help to mitigate risk.*

#### **2. Vivaria lighting control systems should operate independently of the overall facility/building.**

Lutron recommends separating the lighting control system for the vivarium from the lighting control system for the rest of the building. If a single lighting control system is used for the entire building, separate user rights should be established for the research team.

*System considerations — The sensitive nature of data required for regulatory approval may demand programming or operation access exclusive to the research team. A separate lighting control system is typically defined as an individual application installation on a server solely purposed for the aforementioned installation.*

#### **3. Critical and sensitive areas require defined sequence of operations (SOO).**

A written SOO and automation narrative will help establish the required lighting control strategies. Diagrams and illustrations should be used to prevent misunderstanding. Each room type should have it's SOO approved by the research team prior to system quotation.

*System considerations — Vivaria typically have advanced SOO when compared to typical commercial spaces. They often including complex time- clocks, automation overrides, and integrations. To meet an advanced SOO, the lighting system may require advanced conditional programming, sequenced functions, and extensive use of state variables.*

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#### **4. Integrations with other building systems, such as HVAC, building management, security, environmental monitoring, and data storage, are frequently an essential component of the wholistic controls strategy.**

Be certain to understand the integration requirements including:

- What information will other systems need to extract from the lighting control system?
  - Current lighting scene
  - Current state of variables
  - Area occupancy status
  - System devices that are not responding
- Are there any points on the lighting system controlled by a third party?
  - Set scene
  - Set variable state
  - Enable / disable timeclocks
- How will the third party interface with the lighting control system?
  - BACnet over IP
  - RESTful JSON API
- Are there any light- based alarms?
  - Lights too bright or too dim for current scene
  - Lights in wrong scene for variable and occupancy state
- From what system alarms will be raised?
  - Centralizing alarms may increase their effectiveness
- Which system is responsible for historical data retention?
  - What data is required?
  - How long must that data be stored?
  - How do the data formats compare to each other?

*System considerations – Integration between systems requires coordination, ensure to schedule preconstruction meetings with integrating vendors to determine feasibility, function, and scope- of- work. Include commissioning services specific to configuration and testing of integrations. Include commissioning services specific to configuration and testing of integrations.*

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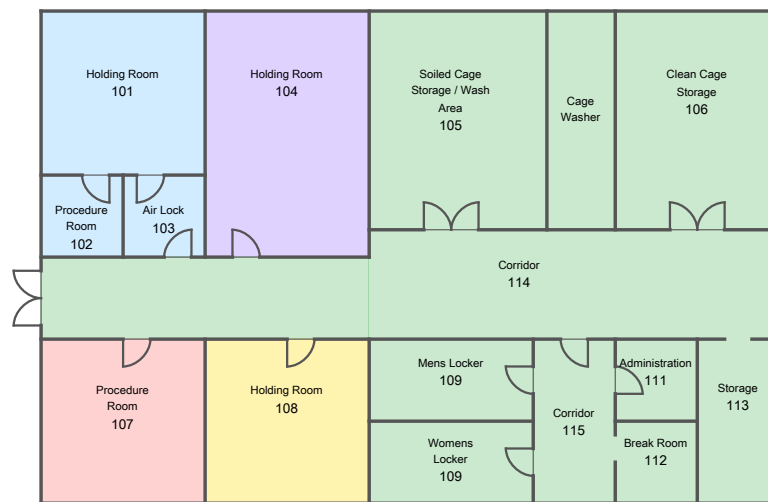
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### 5. System design should prioritize functional independence of research areas.

Vivaria spaces are often broken into distinct working groups. A working group is a set of areas (rooms) that are always working on the same group of experimental subjects, there are no instances where one room in the set is not operationally required while the others are in use.

Failures in environmental control systems can lead to lost or disqualified research, in a lighting system this could mean the lights are uncontrollable. Systems should be designed such that a failure in one work group does not affect any other work groups. In the below example there three Holding Rooms, two Procedure Rooms, two Cage Wash Areas, a Corridor and some administrative spaces; they can be divided into five functional groups.

Rooms **101**, **102**, and **103** all share an exit through the Air Lock. We can make the assumption that those rooms are operationally uniform, the work happening in the Procedure Room is on the subjects held in the connected Holding Room; the Air Lock prevents contamination into or out of those spaces. We can group these rooms together, as a failure in the Holding Room would have an effect on the Procedure Room, and vice-versa. Another way of thinking about why these rooms can be grouped: would making them operationally independent, from a controls perspective, reduce the effect losing one of the spaces would have on research production.



The other three spaces, rooms **104**, **107**, and **108**, cannot reasonably be assumed to co-function. They should all be maintained as independently operating spaces unless explicitly directed.

The **Cage Wash Areas**, **Corridors**, and **administrative spaces** are not sensitive or critical; if the lights were stuck on at 100% it would be inconvenient but would not have any effect on the quality of the research. These areas can be grouped together, a failure in one area cascading into other areas doesn't increase the effect to research production.

*System considerations — The number of independently serviceable systems will be determined by the number of independently functional groups. Breaking the system into smaller sub-systems increases reliability and robustness, but also increases costs; the ideal balance is found when making the system into more groups no longer increases the useful reliability of the system. The above example had five functional groups, this would equate to five independently serviceable systems.*



### **6. Light quality is critical in vivaria**

Sensitive areas commonly require a constant 20-30 foot-candles during simulated “Day”, and a low-intensity red or yellow light during simulated “Night”. Another frequent requirement is simulated dawn and dusk transitions, i.e. smooth ramping up and down of light level between day and night light settings respectively.

Fixture components are the primary contributors to achieving required light levels without flicker, variation, or interruption. Many fixtures that produce consistent high-quality light in steady state still exhibit less than ideal performance during transitions. Compatibility between fixtures and their controllers is essential in producing quality light output.

Cycling between artificial daylight and the absence of perceptible light is often used to stimulate circadian rhythm in subjects. Photoreceptors, and therefore their spectral absorption, vary by species; consequently, luminaire spectral power distribution should be considered when choosing fixtures.

Additional sources of light, such as viewing windows and/or computer monitors in the space, should also be considered. Accounting for and controlling environmental conditions, including all sources of light, is pivotal in research validation.

*System considerations — Determine the maximum and minimum foot-candle level for each room type and validate that the fixtures and controls can reliably produce required light without undesired photic effects. Include one or more light level tuning visits to calibrate light levels prior to occupancy.*

### **7. Critical spaces require continuous power.**

Power Sources for lighting can typically be divided into three categories: Normal, Emergency (Egress), and Critical.

Normal lighting is the most common lighting and is the predominant source of illumination in most spaces. It is powered from a utility provider without a backup, a loss of utility power equates to a loss of normal lighting.

Emergency or Egress lighting is intended to provide illumination necessary to safely exit a building. It may be part of a system or standalone devices. The operation commonly involves override a lockout, lights going to full brightness with manual and automated controls disabled.

Critical lighting primarily serves spaces in which lighting levels essential to completion of high priority tasks. This lighting is often found in surgical theatres or other places where variation of light level or loss of control may cause disruptions with costly consequences.

In vivaria it is essential to maintain normal schedules and manual control so as to not disrupt animals, data collection, or research procedures. Most electronic systems have a delayed start, meaning that full function is not instantly resumed after power cycle. Therefore luminaires and controls of critical or sensitive areas should be powered from an uninterruptible power source to preclude loss of function resulting from loss of utility power.

*System considerations — Power sources for vivaria environmental control systems should be uninterruptible. System design should account for research team’s operational needs during a loss of utility power.*

### **Additional Considerations**

#### **8. Local manual control should always be included.**

Local manual control, such as a wall- mounted keypad or keyswitch, should provide automation override when necessary. Many electric codes require local control devices to ensure occupant safety. Digital controls can provide a simple interface to trigger complex actions. Engraved buttons with status indication can provide visual feedback to inform staff of room lighting status without entry. Locating keypads outside of sensitive areas can reduce the number of air penetrations and simplify sanitation processes.

*System considerations — Wired keypads with indication LEDs should be included for each space to allow for manual control. Control system should support various button functions and keypad layouts. Factory engraving or other permanent marking should be provided. Control system should support methods to mitigate inadvertent activation; prolonged button presses or protecting the control with a locked cover are examples of such protections. Keypads should allow physical barriers, such as silicone cover, to support sanitation of touch surfaces.*

#### **9. Access to system wide controls and configuration software should be limited to qualified individuals.**

Many lighting control platforms offer advanced user interfaces that can be used to monitor and control the system. These interfaces provide power- users access to verify system health and make minor configuration changes, e.g. how bright the lights get during the day, when necessary. Creating individual user accounts can ensure that the correct privileges are given to the correct users. Consideration should also be given to how and from where users will access the interface.

*System considerations — Lighting system front- end interface should allow for individual system- user accounts. Individual system- user accounts should have configurable permissions that restrict actions that the user account can perform and areas that they can perform aforementioned actions on. User interface should be accessible from location convenient to research staff.*

#### **10. Avoid ultrasonic occupancy sensors in and around sensitive areas.**

Similar to how animals have different color vision than humans, they also have different auditory abilities. Ultrasonic, sounds having a frequency above human perception, sensors produce a sound that is often audible to animals. The sound can disrupt animal activity which may adversely affect research.

*System considerations — In spaces where occupancy sensors are required, Passive Infrared (PIR) sensors are recommended. Ultrasonic or dual- tech sensors may have an adverse effect on animals in the lab.*

### **11. Window treatments, if used, are part of lighting controls.**

Most vivaria do not have windows, due to the sensitive nature of animals' eyes; those that do often house larger animals such as nonhuman primates, cats, dogs, and sheep. If light is able to enter a sensitive area, from outside or otherwise, it should be controllable, the same as artificial lighting in the area. Automated window treatments can ensure that the correct amounts of light are able to enter the space at the correct times for the correct durations. Window treatment automation allows for logging of window treatment operation, which may be required for research reporting.

*System considerations — Automated fenestration treatments, when used, should be incorporated into the lighting control system. Check operational requirements and determine what functions are needed from the shading system, some manufacturers do not support adjustable or granular positioning. Motors may need to transmit positional information to the control system to support conditional programming.*

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## Illumination Control Overview for Vivaria

**Examples of how different lighting control systems from Lutron Electronics will meet various vivarium control requirements.**

<b>System Feature Matrix</b>	Quantum	Athena	Vive	QS Standalone <sup>1</sup>
Local Manual Controls	✓	✓	✓	✓
Full Dimming Range	✓	✓	✓	✓
Time Clock	✓	✓	✓	✓
Passive Infrared Occupancy Sensors	✓	✓	✓	✓
Individual Lamp Control	✓	✓	✓	✓
Centralized Control Point	✓	✓	✓ <sup>2</sup>	
Advanced Integration <sup>3</sup>	✓	✓	✓	
Shade control	✓	✓		✓
Advanced Conditional Programming	✓	✓		
Override Timer	✓	✓		
Time Clock Catch-up	✓	✓		
Alerts <sup>4</sup>	✓		✓	
Historical Data Retention	✓		✓ <sup>2</sup>	
Individual User Rights	✓		✓ <sup>2</sup>	
Light Level Monitoring	✓			

<sup>1</sup>QS Standalone refers to QS devices such as QS GRAFIK Eye and Energi Savr Nodes being used without a central control hub such as a Quantum or an Athena processor

<sup>2</sup>Requires Vive Vue

<sup>3</sup>Advanced integration refers to BACnet and/or API integration. Feature sets are not identical across platforms, refer to system Protocol Implementation Control Statements or applicable integration document for more detail

<sup>4</sup>Alerts available and method of delivery varies by system.

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## Illumination Control Overview for Vivaria

### **Specification guidelines to mitigate risk and optimize reliability, robustness, and functionality.**

Lutron recommends Quantum Total Light Management system for vivaria, it has been deployed into some of the most advanced research facilities around the world. Regardless of the manufacturer chosen to supply lighting controls the points below can be used to ensure success.

1. Lighting control manufacturer for vivaria spaces shall have minimum ten years experience implementing lighting controls in vivaria spaces.

*For more information see **Essential Design Consideration 1***

2. Lighting control system for vivaria spaces shall operate independently, and have no interdependence of lighting control system(s) for non-vivaria spaces.

*For more information see **Essential Design Consideration 2, Essential Design Consideration 5, and Additional Consideration 9***

3. *The server provided for use by the vivaria lighting control system shall be sole- purposed, running only software required for operation of the vivaria lighting control system.*

*For more information see **Essential Design Consideration 2, Essential Design Consideration 4, and Additional Consideration 9***

4. *All lighting controls components and luminaires serving vsensitive or critical vivarium areas shall be powered from a UPS (Uninterruptable Power Source).*

*For more information see **Essential Design Consideration 7***

5. *Networked Lighting Control System shall be able to support conditional logic and multifunctional keypads*

*For more information see **Essential Design Consideration 3 and Additional Consideration 8***

6. *Each vivarium area, or working group, shall have non- interdependent hardware.*

*For more information see **Essential Design Consideration 2 and Essential Design Consideration 5***

7. *Vivarium areas, or working groups, shall be individually re-programmable.*

*For more information see **Essential Design Consideration 2 and Essential Design Consideration 5***

8. *Manual Override controls with status feedback shall be provided and located immediately outside of sensitive areas.*

*For more information see **Additional Consideration 8***

9. *Lighting control system shall support integration via BACnet and/or RESTful JSON API.*

*For more information see **Essential Design Consideration 4***

### **Specification guidelines (continued...)**

10. Fixtures shall be capable of producing light output with continuous, flicker-free dimming from 100% to 1%.

*For more information see **Essential Design Consideration 6***

11. Fixture manufacturer shall provide documentation of compatibility and performance of luminaires with dimming controllers to be installed.

*For more information see **Essential Design Consideration 6***

12. Occupancy sensors shall not use ultra-sonic emitters.

*For more information see **Additional Consideration 10***

13. Motorized window treatments shall support bidirectional data and provide position information to the lighting control system.

*For more information see **Additional Consideration 11***

14. Lighting controls manufacturer shall develop and implement testing procedure for all sensitive areas to ensure accurate system functionality.

*For more information see **Essential Design Consideration 1***

15. Lighting controls manufacturer shall provide a service day to discuss system function and testing methodology with owner's representative or commissioning agent.

*For more information see **Essential Design Consideration 1***

16. Commissioning of lighting control system shall be documented to include date when each room was successfully tested ready for turn-over.

*For more information see **Essential Design Consideration 1***

17. Lighting control manufacturer shall provide Field Service response, on-site or remote, to warranty issues within 24 hours of receiving report.

*For more information see **Essential Design Consideration 1***

### **Regulations, Recommendations, and Accreditations – Key Players**

#### **National Institute of Health (NIH): Office of Research Facilities**

The NIH Office of Research Facilities supports the NIH mission by providing, maintaining, and operating safe, healthy, and attractive facilities.

#### **NIH Office of Animal Care and Use**

The Office of Animal Care and Use administers the NIH intramural program of Animal Care and Use. This includes managing the Animal Welfare Assurance and programs of compliance.

#### **Institute for Laboratory Animal Research (ILAR)**

A unit of the National Academies of Sciences, the mission of ILAR is to evaluate and to report on scientific, technological, and ethical use of animals and related biological resources. ILAR seeks to identify practices that provide for excellence in the welfare of animals used for these purposes, recognizing their moral value while achieving high- quality science.

#### **Canadian Council on Animal Care (CCAC)**

The Canadian Council on Animal Care (CCAC) is the national peer-review organization responsible for setting, maintaining, and overseeing the implementation of high standards for animal ethics and care in science throughout Canada.

#### **Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)**

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

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### **Guides and Standards Relating to Lighting Design in Vivaria**

#### **Guide for the Care and Use of Laboratory Animals – 8th edition – Institute for Laboratory Animal Research (ILAR)**

Chapter 3/ENVIRONMENT, HOUSING, AND MANAGEMENT/Terrestrial Animals/Illumination pg. 47

Chapter 3/ENVIRONMENT, HOUSING, AND MANAGEMENT/Aquatic Animals/Illumination pg. 81

#### **Highlights**

- Inadvertent light exposure during the dark cycle should be minimized or avoided. A timecontrolled lighting system should be used to ensure a regular diurnal cycle, and timer performance should be checked periodically to ensure proper cycling.
- The most commonly used laboratory animals are nocturnal. Because the albino rat is more susceptible to phototoxic retinopathy than other species, it has been used as a basis for establishing room illumination levels.
- Light levels of about 325lux (30ft- candles) about 1.0m (3.3ft) above the floor appear to be sufficient for animal care and do not cause clinical signs of phototoxic retinopathy in albino rats, and levels up to 400lux (37ft- candles) as measured in an empty room 1m from the floor have been found to be satisfactory for rodents.
- Thus, for animals that have been shown to be susceptible to phototoxic retinopathy, light at the cage level should be between 130 and 325lux.
- Provision of variable- intensity light controls might be considered as a means of ensuring that light intensities are consistent with the needs of animals and personnel working in animal rooms and with energy conservation. Such controls should have some form of vernier scale and a lockable setting and should not be used merely to turn room lighting on and off.
- Gradual changes in room light intensity are recommended, as rapid changes in light intensity can elicit a startle response in fish and may result in trauma.



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### **Guides and Standards Relating to Lighting Design in Vivaria**

#### **2016 Design Requirements Manual (Revision 1.4) – National Institute of Health (NIH)**

Section 10.7: Lighting

#### **Highlights**

- LED or fluorescent lamps are recommended in all but the most critical color-rendering applications
- LED Driver: General requirements for LED drivers are as follows:
  - Listing: Listed with UL; certified by lighting Electronic Testing Laboratories (ETL)
  - Efficiency: Higher than 90%
  - Power Factor: 0.90 or above
  - Sound rating: Class A per UL 935-84
  - RFI/EMI: Comply with Federal Communication Commission (FCC) Title 47 CFR Part 18
  - Total Harmonic Distortion: Less than 10%
  - Transient Voltage Protection: Comply with IEEE C62.41.1 and IEEE C62.41.2
  - Dimming: Dimmable driver shall be capable of dimming light output to 10% of full light output without producing visible flicker.
  - Warranty: Minimum five years

### **Guides and Standards Relating to Lighting Design in Vivaria**

#### **Guidelines on Laboratory Animal Facilities – Canadian Council on Animal Care (CCAC)**

8.3 Lighting Fixtures: Guideline 75

12.2 Light

#### **Highlight**

- All light fixtures throughout the animal facility should be vapor-proof.
- Bright light, however, should be avoided. For animal rooms that are to house common species of laboratory animals, the normal light intensity should be approximately 325 lux measured at one metre above floor level.
- An override control will permit increasing the intensity up to a maximum of 1000 lux for limited periods of time. The intensity should automatically go back to the lower level after a set period of time (commonly 20 minutes).
- Most species held for maintenance do well on a 12:12 light cycle. Animals' endogenous rhythms can be significantly skewed if the dark phase of the cycle is interrupted.
- Consistency in the diurnal cycle is often critical to reliable research results. In certain circumstances, an abrupt change between light and darkness is not acceptable, and the crepuscular periods of dawn and dusk must be simulated.
- LEDs have been deemed safe for use with laboratory rats.

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Association of Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

### **Accreditation**

The AAALAC International accreditation program evaluates organizations that use animals in research, teaching or testing. Those that meet or exceed AAALAC standards are awarded accreditation.

The accreditation process includes an extensive *internal* review conducted by the institution applying for accreditation. During this review, the institution creates a comprehensive document called a “Program Description” which describes all aspects of the animal care and use program (policies, animal housing and management, veterinary care, and facilities). The Program Description is then submitted to AAALAC.

Next, AAALAC evaluators (members of AAALAC’s Council on Accreditation) review the Program Description and conduct their own comprehensive on-site assessment. The site visitor’s report is then reviewed by the entire Council on Accreditation, and accreditation status is determined. If deficiencies are found they are outlined in a letter, and the institution is given a period of time to correct them. Once the deficiencies are corrected, accreditation is awarded. The entire process is *completely confidential*.

After an institution earns accreditation, it must be re-evaluated every three years in order to maintain its accredited status. Currently more than 1000 organizations in 49 countries have earned AAALAC accreditation.

Accreditation benefits an institution and the animals in its care in many ways. And each time a new organization becomes accredited, it helps to raise the global benchmark for animal well being in science.

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Source for the following quotes — <https://www.fda.gov/about-fda/fda-basics/what-does-fda-do>

- Protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations

FDA's responsibilities extend to the 50 United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, American Samoa, and other U.S. territories and possessions.

You may deduce from the above statement the FDA is not responsible for vivarium environmental standards. It is responsible for the safety, efficacy and security of the products developed as a result of ongoing research. Therefore, how the research and testing was conducted, and the conditions in the research environment, all have an influence on the test validity.

While the FDA does not directly mandate the environmental conditions of vivaria, it is more likely to deliver a position FDA judgment when the vivarium research can show minimum disruptions to its testing, proof of redundant environmental measurements, and secure, high integrity data. Conversely, anything that increases disruptions, allows for environmental measurement questions, or jeopardizes the data integrity could help invalidate the testing and produce a negative FDA judgment, resulting in potential lost revenue of millions or even billions of dollars.

### **Note on FDA Involvement in the Vivarium Environment**

The FDA, while not involved in regulations of Animal Research or the Animal Research Facilities, is involved in the testing of any results that will affect humans. A requirement of three years of test data are commonly maintained for FDA approval.