Technical Report

Illumination Control Overview for Vivaria

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Abstract —

Vivaria typically represent a relatively small piece of a larger application, and because the lighting requirements are typically so different from the rest of the project, vivarium lighting specifications can be particularly challenging. Specifiers may jeopardize their success with the total job because they do not have expertise in this one, specific aspect of lighting design.

In this whitepaper we will

- Define "vivarium" and discuss their unique lighting requirements
- Present and discuss specific questions to ask to prepare an appropriate lighting specification
- Identify lighting systems designs that minimize risk and help ensure reliability and functionality within the facility
- Look into the regulatory requirements and illumination recommendations.

The goal of this whitepaper is to help lighting professionals with extensive lighting design experience, but little or no experience with vivaria, 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:

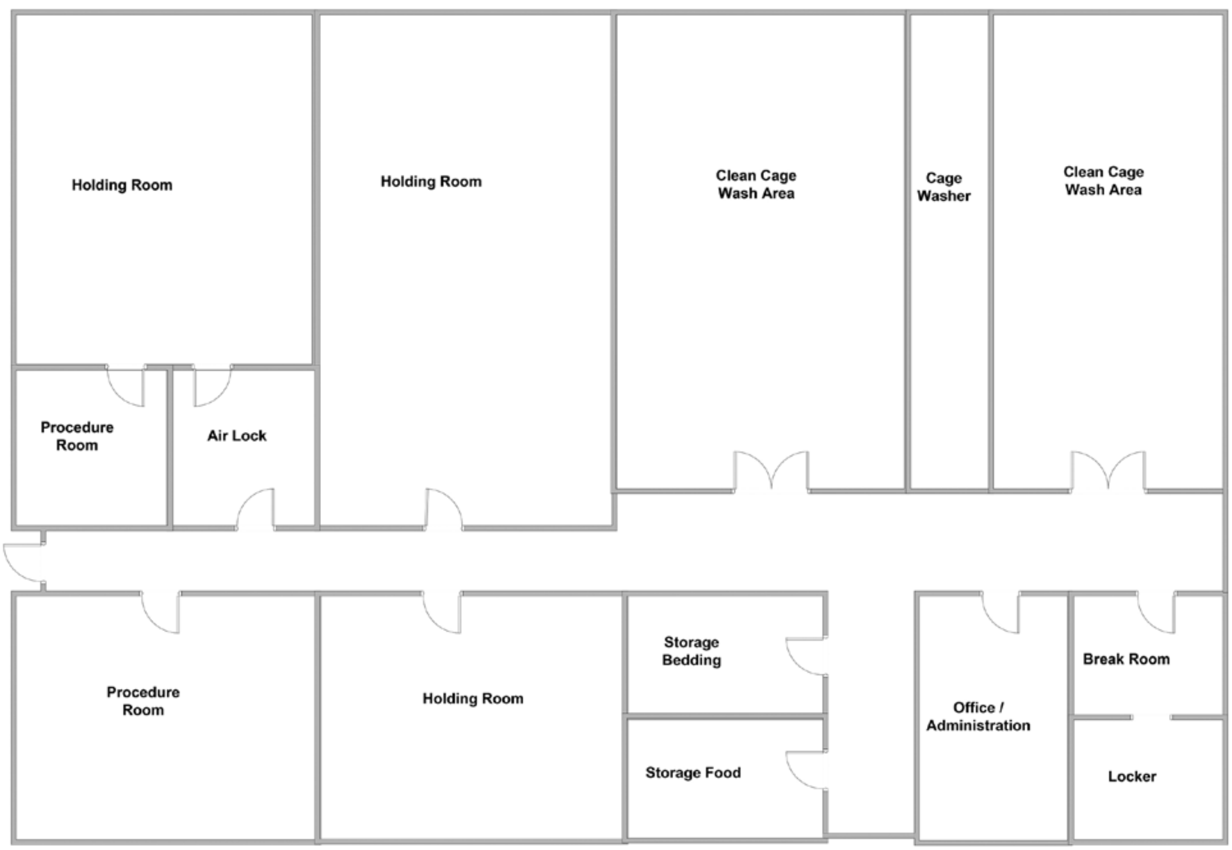
- Operator control stations
- Advanced BMS integration
- Full-range dimming
- Time clock
- Time clock catch-up
- Override timer
- Individual lamp control
- Light level monitoring
- Alarm
- Historical data retention
- Shade control

What is a Vivarium?

A vivarium is a place, such as a laboratory, where live animals or plants are kept under conditions simulating their natural environment, as for research.

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 is focused 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 Area, Feed Storage Room, and Bedding Storage Rooms. Lighting control is most critical in the Animal Holding Rooms and Procedure Rooms.



Most vivaria are not stand-alone buildings, but rather sections (usually confined to a single floor) of a larger building. The special environmental requirements of the vivarium space are not generally representative of the rest of the building, and neither is the control over that environment. While the rest of the building's environment is the responsibility of the end user and the end user's facility group, day-to-day control of the vivarium is the usually the responsibility of the research team.

Lighting manufacturers frequently work with the Architects, Lighting Designers, Electrical Engineers, and Electrical Contractors - professionals who are familiar with lighting control requirements for most types of buildings but frequently have little or no experience with lighting design and control requirements for vivaria. The risk in applying traditional, commercial lighting control design to vivaria is in delivering a system that cannot comply with the research team's needs, often leading to significant additional costs and struggles with responsibility for those costs. It is critical to work with a lighting control manufacturer with a working knowledge of vivarium requirements, and the ability to propose and implements complementary lighting control solutions.

This whitepaper will contribute to an informed dialog that can be used to achieve an appropriate lighting specification, alleviate callbacks and revisions, or ultimately avoid lighting systems that do not adequately support scientific discovery.

Essential Design Considerations

No two vivaria are exactly alike. Unique research demands unique lighting and control protocols. The answers to these questions will help to frame up the right specification, work to reduce additional costs due to last minute changes, and will help ensure that all critical issues have been addressed.

1. **Each holding and procedure room will generally have a unique sequence of operations.**

   A written sequence of operations, agreed upon by the research team prior to a systems quotes, for each room type in the space– holding rooms, procedure rooms, cage wash area, feed storage/bedding storage room — will help establish the required lighting control strategies.

   System considerations — The necessary Sequence of Operation (see page xx) for overrides, time clocks, and BMS integration is usually very advanced compared to the rest of the building. There are also special requirements for time clocks or BMS integration. Advanced conditionals, sequences, and extensive use of state variables may also be required. Choose a total light management system that allows for additional programming both off and on site.

2. **Vivaria often require a lighting control system that is independent of the overall facility/building.**

   Determine whether the lighting control system can be integral to the rest of the building lighting system, and if so, will you need to establish separate user rights or overrides 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 a separate server and database. The system may also benefits from al local control station that enables the Vivarium Supervisor to tweak time clock durations and light levels.

3. **If a centralized light management system is specified, decide whether the lighting system software should only be available from the terminal in the vivarium area and who will have user rights.**

   System considerations — With digital control systems, the only way to fully restrict user access is a separate system, or a separate server. Otherwise, anyone with Administrator access will always have access to the entire system. Make sure the specified lighting control system can limit and allow access as necessary.

4. In vivaria, dimming is often required to simulate dusk and dawn transitions.

Ask how flexible the lighting control system needs to be to accommodate. For example, is a rapid change from on to off acceptable, or will a gradual change of light level better simulate the natural environmental change? What is the maximum time period necessary between full on and full off?

System considerations — Transitions can be accomplished with timeclock or sequence controls, or they can be programmed to follow the actual movement of the sun. Usually a simple 12 ON/12 OFF cycle is required but the transition time, or a detailed 24-hour sequence may be a requirement. This highlights the need for a detailed sequence of operation before the system is bid to ensure system capability, and to avoid additional costs.

5. If there are windows in the holding or procedure rooms, are shades required to accommodate full blackout capability, and do they need to be automated?

System considerations — Most Vivaria do not have windows because of the sensitive nature of animals' eyes but some do, especially those that house larger animals, such as nonhuman primates, dogs, cats, and sheep. Motorized, automated shades can incorporated into the total light management system, depending on the system manufacturer. Check integration requirements, and choose a lighting and shade control system that can comply with that systems need.

6. Integration with other building systems, such as HVAC, security, and data storage systems, is frequently an essential requirement for the lighting control system.

Be certain to understand the integration requirements including what type of HVAC control will be used, what type of time clock wlll be used, how will data be stored, and from what system will any alarms or other reports be generated?

System considerations — Integration is extensive in most vivarium facilities. Establish ownership of essential information early in the specification process. Which systems:

– Record sensor and other data for regulatory submission?

– Set and send alarms?

– Is responsible for the time clock control?

The lighting control system may be required to communicate system information to the BMS through BACnet IP but may not be able to report button pushes. These information-and-reporting relationships usually require additional integration coordination visits. To make the process as smooth as possible and to avoid unnecessary costs, the sequence of operation for the BMS is vital before the system is quoted. The Sequence of operation for the BMS may be either in CSI MasterFormat Divisions 26 (Electrical), 23 (HVAC), or 25 (Integration)

7. Light Levels are critical in vivaria. LPD is commonly 20–30 FC constant within holding or procedure areas.

Make sure your system's low-end can achieve this FC rating without flicker, variation, or interruption.

System considerations — Determine the maximum and minimum foot candle level for each room type (such as holding rooms, procedure rooms, cage wash areas, feed-storage and bedding storage, and necropsy rooms). Plan to include a tuning visit to ensure/verify light levels prior to occupancy.

8. Time clock control in vivaria is usually 12 hours "ON" and 12 hours "OFF", but be certain to establish the type of time clock control

Is it a simple, diurnal time clock of 12 hours on and 12 hours off being used? If an advanced time-of-day simulation is used, what are the required event duration times?

System considerations — The solution will depend on whether the lighting control system is providing the time clock, or it is part of the BMS system. As was discussed in section 4, a simple 12-hour ON, 12-hour OFF is typical, but a more detailed 24-hour sequence may be required. Again this highlights the need for a detailed sequence of operation before the system is bid to ensure system capability, and to avoid additional costs.

9. Occasionally, systems may require manual time clock overrides. Consider how the lighting control system should respond.

Will it need a "catch-up" function to go back to proper cycle when override timer is over? Should the system wait for the next time clock event before changing light level or reverting to the defined scene for current time?

System considerations — This function is solid capable by Quantum when the Quantum Time Clock is used and not the BMS for the project.

10. Manual override timer controls can be used to adjust lights for out-of cycle situations, but should be active for no longer than 60 minutes, and commonly for 20 minutes.

Decide if manual control required outside each holding room, and what is the acceptable duration for the interrupt periods.

System considerations — Sequence of Operations for overrides is many times very advanced for holding rooms in particular. Advanced conditionals, sequences, and extensive use of state variables may be required. Allow for additional programming both off and on site. This highlights the need for a detailed Sequence of Operation before quote to avoid additional costs.

11. Out-of-cycle lighting entry may employ different colors, such as red or yellow lamps instead of white lights.

Determine what fixtures are being used, and how they will be controlled. If red and/or yellow lamps are used, does each color lamp require separate control?

System considerations — In situation where fixtures have a combination of white and colored lights, control strategies have to be considered up front. White lights are used to simulate daylight, but at a high output white lights can adversely affect animals and ultimately the experiment results. Colored lights, such as red, do not affect most animals. Fixtures may have a combination of white and red lights where multiple ballasts or drivers are needed. Typically while lights will be dimmed while colored lights will be switched. Identify this need early in the specification process.

12. Light level monitoring be required and data may need to be recorded.

Which system will collect and store this data (lighting system, BMS system, or both)?

System considerations — Since most holding and procedure rooms do not have windows, daylight will not typically need to be monitored, but electric light level is monitored by sensors to ensure it meets the proscribed 20-30 FC. Higher levels can be programmed to activate an alarm when they are recorded. The sensor may be integrated the lighting system or the BMS system. Ensure that the specified lighting management system can send recorded data from its indoor sensors to the BMS system, or record it internally and send an alarm in the form of an email. This requirement may effect startup and the bill-of-materials (BOM) for the server, sensors, and network communications, and should be established prior to quote to avoid additional costs.

13. System operation is always important, but in vivarium, a malfunctioning system could put years of research and data in jeopardy.

Alarms have to be in place to quickly and efficiently alert research staff of any system malfunction. As part of the specification process, identify what functions or levels need to be alarmed, how the alarms will be communicated (email, screen popup, other indicator), and whether each building system will be responsible for its own alarms, or whether they will all be funneled through one system.

System considerations — Centralized lighting control systems can be used that have the ability to email alerts and record alarms. In general, the lighting control system's email will need access to an email server (this will require IT integration services), or the lighting control system can relay the collected data, in real time, to the BMS system (this will require BMS integration services) to create and deliver an alarm.

14. Historical data and experimental results will have to be retained for a minimum of three years.

Ask if the data retention will be handled through individual systems (lighting, BMS) or whether one system will maintain stored data.

System considerations — The requirement is for Lutron in addition to or in lieu of the BMS system a RAID server is recommended for redundant data storage.

* Note, in general DO NOT enable the After Hours function where lights will turn off in a predetermined amount of time after any manual override. The Blink Warning that indicates an OFF action is about to occur may have a negative impact on the animals.

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

	Quantum	QSG	QSN	TriPak
Operator Control Station	✓			
Advanced BMS Integration	✓			
Full Dimming Range	✓	✓	✓	✓
Time Clock	✓	✓	✓	
Time Clock Catch-up	✓			
Override Timer	✓			
Individual Lamp Control	✓	✓	✓	✓
Light Level Monitoring	✓			
Alarm	✓			
Historical Data Retention	✓			
Shade Control	✓	✓	✓	

Specification "Rules-of-Thumb" to minimize RISK; reliability, robustness, and functionality.

1. Specify Lutron Quantum® Total Light Management™ systems. *Quantum is the only system with the versatility to meet the research team's requests and is the only system with the advanced BMS integration requirements of a Vivarium.*
2. Sensitive Vivarium Areas, animal holding rooms and Procedure Rooms, should have their own Quantum QP2 or QP3 hubs. *Independent processors isolate system failures, and allow each sensitive vivarium area complete operational independence.*
3. Sensitive Vivarium Areas, animal holding rooms and Procedure Rooms, should make each room its own subsystem in the Quantum database. *Independent subsystems allow programming to be uploaded to the processor with no effect on lighting operations in other areas.*
4. *Separate the vivarium system from other systems in the building. Do* not use one system for both Vivarium and other spaces. This eliminates any appearance of unauthorized input for testing procedure authentication.
5. Make sure the vivarium has its own dedicated server and reporting license. Environmental verification is important to testing validation. *Although a BMS may be required for environmental reporting, a second source is warranted to ensure data accuracy and protect against error.*
6. Require the Quantum QP2 or QP3 hubs, and all Lutron ESN controls, to be backed up with a UPS (uninterruptable power source) making sure that the processor will never lose power. This is different than emergency power, which responds to power interruption. *Standard emergency power from an emergency transfer switch will have a delay between loss of normal power and delivery of emergency power, causing lights to go to emergency level for 15 to 30 seconds disrupting and potentially damaging the animals. This will not be the case when using a UPS.*
7. Wired devices are preferable because they do not use batteries. *Wired devices completely eliminate any RF impact on animal behavior, and wireless daylight sensors that are used for light level alerts do not transmit at every level change .*
8. If the Vivarium light-level-alarm feature is required, include the sensor placement service for proper sensor placement. Light level validation should include placement and functional testing for research submission. *Only use keypads with LEDs for status feedback. Do not use Pico battery-powered controls, wired or wireless. Keypads located outside sensitive areas, holding and procedure rooms, should show team members the state of the room before entering or changing state.*
9. Require remote access is available for support. *Any disruption in the testing environment can affect research submission and should be dealt with as soon as possible. Remote access, regulated only by the research team, can allow them to handle many issues and efficiently.*
10. Include three days of required of testing and review of all animal-holding areas before turn-over to the customer. *Lutron will validate all system operation, with camera feed to record these areas as part of our testing and review. This is to fully validate that the lighting system is working as required by the research team and documented for testing validation at research submission.*
11. Require "Platinum Service Plan" for Vivarium part of the building (at a minimum — Platinum service plans are available for all Quantum total light management systems). *Any disruption in the testing environment can affect research submission and should be dealt with as soon as possible. Lutron Platinum Service Plans allows for the best response time from Lutron onsite personnel.*

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.

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.

Accreditation Associations;

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.

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 time-controlled 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 325 lux (30 ft-candles) about 1.0 m (3.3 ft) 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 400 lux (37 ft-candles) as measured in an empty room 1 m 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 325 lux.
- 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.

Guides and Standards Relating to Lighting Design in Vivaria

Design Policy Guidelines — **National Institute of Health (NIH)**

Volume 3: Animal Research Facilities / Programmatic Goals / B.2.4 Lighting

Volume 3: Animal Research Facilities / Design Criteria / D.5.9 Lighting Loads / D.7.3 Lighting / D.7.3.1 Lighting Controls

Highlights —

- Natural light is not recommended in areas that will house animals that require regulated lighting cycles. Windows may be desired in areas that house large animals such as nonhuman primates, dogs, or farm animals
- Fluorescent lighting is recommended in an animal facility. Lighting should be waterproof, recessed, ceiling mounted, and sealed and caulked top prevent vermin infestation
- Lighting control is a major consideration, particularly in small-animal holding rooms. Lighting should be centrally controlled and monitored at the room level. Monitoring of the lighting control system should be independent from the method used to control the lights. Consideration should be given to direct measurement of room illumination or monitoring the electrical circuit feeding the room light. The ideal system would provide a local warning light alarm and, if required, remote audible alarms signaling lighting failures
- Consideration should be given to providing a warning light outside the rooms that are on automatic timed lighting to indicate that the room is on the dark cycle
- All small-animal holding rooms should have individual light controls and light timers.

Guides and Standards Relating to Lighting Design in Vivaria

Design Requirements Manual — **National Institute of Health (NIH)**

Section 10-8: Lighting

Highlights —

- When emergency power is available, 50% of the fixtures in these rooms shall be connected to emergency power.
- Feed-through and/or tandem wiring of fixtures shall not be permitted.
- Fluorescent lamps are recommended in all but the most critical color-rendering applications. Ballast shall be solid-state electronic. Ballast shall be UL listed, Class P thermal rating, and Class A sound rating; Underwriter's Laboratories (UL), and labeled by Certified Ballast Manufacturers Association (CBM). Ballast shall have an operating frequency of 20 kHz or greater. Ballast shall contain no polychlorinated biphenyl (PCB). Light regulation shall be ±10% with nominal ±10% voltage variation. Lamps shall be operated in instant start mode. Ballast shall be designed to withstand transients described in IEEE Standard 587, Category A. Ballast temperature rise shall not exceed 25 °C over 40 °C ambient. Ballast shall meet Federal Communications Commission (FCC) regulations, Part 18. Ballast shall have a minimum 5-year warranty. Ballasts shall have less than 10% total harmonic distortion. Remote ballasts shall be considered in magnetic, radio frequency and electrophysiology areas. The A/E shall take low THD ballast inrush current into consideration when calculating lighting circuit loads.
- UL listed, damp location, factory sealed and gasketed fluorescent lighting fixtures with three T-8 lamps per fixture, in sufficient quantities per room to achieve the required illumination levels shall be provided in small animal and rodent holding rooms.
- Minimum IP65 rated
- Where closed circuit television (CCTV) cameras are present, occupancy sensors shall not be the sole lighting control. One lighting fixture within CCTV coverage area shall be controlled by a local key switch, at a minimum.
- Animal holding room lighting control shall be provided by a programmable lighting control system, either using the BAS or a standalone system.
- The system selected shall provide a terminal for user control and adjustment of lighting cycles within the vivarium supervisor's office, or at another location within the vivarium as directed by the user.
- Local engineered override switches shall also be required to function as indicated under each species lighting operation.
- Confirm if dimming control to simulate a dusk and dawn circadian cycle is required.

- Though not required for AAALAC accreditation, all holding rooms may require monitoring to proof and report on lighting cycle function within each room if required by the veterinary program direction. Monitoring requirements such as sensor type, location and proofing of on-off or illumination level functions per holding room shall be determined on a per project basis.
- Diurnal lighting cycle control typically provides a lighting cycle of 12 hours “ON” and 12 hours “OFF”, but shall be adjustable to be able to change either cycle duration, or provide for multiple cycles in a single day at user discretion and adjustment.
- One local engineered override switch shall be required outside each holding room door to provide a caretaker cycle. This engineered override switch shall circumvent the programmable lighting panel controls diurnal cycling for a user adjustable time period of between 0 to 60 minutes, and then have the programmable lighting control revert back to its normal diurnal cycle as previously programmed.
- Though not required for AAALAC accreditation, an additional single lamp lighting fixture may be required for out-of-diurnal-cycle entry, with same characteristics, power requirements and mounting as required based on holding room applications, if required by the veterinary program direction. The single lamp shall be provided with a red (or possibly other color) sleeve, or filmed lens as directed by the veterinary program direction.

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

Highlights —

- 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 has been deemed safe for use with laboratory rats.

Rules of Accreditation —

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

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 950 organizations in 40 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.

Note on FDA Involvement in the Vivarium Environment

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

"FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

Finally, FDA plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats".

Source; http://www.fda.gov/AboutFDA/Transparency/Basics

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.