

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 system 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

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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 areas, feed storage rooms, 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.

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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 implement 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.

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Essential 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, work to reduce additional cost 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 (SOO).

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

System considerations — Vivaria typically have a more advanced SOO, as compared to the rest of the building, which includes overrides, time clocks, and BMS integration. To meet this advanced SOO, the lighting system may require advanced conditionals, sequences, and extensive use of state variables. Remote access, regulated by the research team, is recommended so programming changes can be made quickly if necessary.

2. Vivaria often require a lighting control system that is independent 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 a separate server and database. The system may also benefit from a 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, 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.

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

Consider how flexible the lighting control system needs to be to accommodate dusk and dawn transitions. For example, is a rapid change from on to off acceptable, or will a gradual change of light level better simulate the natural environmental transition? 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 hours on /12 hours off cycle is required, but detail on the transition time or a detailed 24-hour sequence, may be a requirement. This highlights the need for a detailed SOO 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, consider whether shades are required to accommodate full blackout capability, and whether the shades 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 be 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 system's 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 will be used, how data will be stored, and from what system any alarms or other reports will 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?
- Are 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 SOO for the BMS may be either in CSI MasterFormat Divisions 26 (Electrical), 23 (HVAC), or 25 (Integration).

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7. Light levels are critical in vivaria. LPD is commonly a constant 20-30 FC 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? 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 if it is part of the BMS. 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 SOO 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? 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, which indicates an OFF action is about to occur, may have a negative impact on the animals.

System considerations — If time clock events will be managed by the BMS, consider whether the BMS has the catch-up function.

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

System considerations — Particularly for holding rooms, the SOO for overrides is typically advanced and may change based on time of day. Advanced conditionals, sequences, and extensive use of state variables may be required. Remote access is recommended so that programming changes can quickly be made from an off-site location if necessary. This highlights the need for a detailed SOO prior to 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 situations 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, white 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, 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 prescribed 20-30 FC. Higher levels can be programmed to activate an alarm when they are recorded. The sensor may be integrated into the lighting system or the BMS. Ensure that the specified lighting management system can send recorded data from its indoor sensors to the BMS, or record it internally and send an alarm in the form of an email. This requirement may affect 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. Reliable system operation is especially important in a vivarium where a malfunctioning system could put years of research and data in jeopardy.

Any lighting control system should have a proven track record of reliability and quality in the given application. However, in the case of unexpected failures, 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 that have the ability to email alerts and record alarms are strongly recommended. 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 (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 — Data retention policies and expectations should be enforced by the lighting control system in addition to, or in lieu of, the BMS. A RAID (Redundant Array of Independent Disks) server and external backup schemes are recommended for redundant data storage.

15. Avoid ultrasonic occupancy sensors.

Ultrasonic occupancy sensors should be avoided in vivaria as their high frequencies may be audible to the animals, and affect the integrity of the results.

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.

16. Manual control should always be included, even if automated controls such as occupancy sensors are used in a space.

Manual control, such as a keypad on the wall, should always be included in vivaria. This allows the lights to be turned on manually if the automated control fails or is inadvertently disabled.

System considerations — Include a wired or wireless keypad in each space to allow for manual control if necessary. Methods can be employed to prevent inadvertent activation of the control, such as only activating the control after a prolonged button press, or protecting the control with a locked cover.

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

	Quantum	QS Standalone ¹	Vive
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	✓		✓ ²
Shade control	✓	✓	
Passive infrared sensors	✓	✓	✓
Advanced conditional programming	✓		
Individual user rights	✓		✓ ²
Local manual controls	✓	✓	✓

¹ QS Standalone refers to QS devices such as QS GRAFIK Eye and Energi Savr Nodes being used without a Quantum hub

² Requires Vive Vue

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Specification “Rules-of-Thumb” to minimize risk and ensure reliability, robustness, and functionality.

1. Specify Lutron Quantum Total Light Management systems. *Quantum is not the only system with the versatility to meet all of the research team’s requests and includes advanced BMS integration requirements of a vivarium.*
2. Sensitive vivarium areas, such as 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, such as animal holding rooms and procedure rooms, should have each room as 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 lighting control server. 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 Energi Savr Nodes, to be backed up with a UPS (uninterruptable power source) making sure that the processor and load controllers 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. 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.*
8. Require that 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 and enabled only by the research team, can allow them to handle many issues efficiently.*
9. Include three days of required testing and review of all animal-holding areas before turn-over to the customer. *Lutron can validate all system operation, with camera feeds as needed, 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.*
10. 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 allow 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.

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.

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

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
- Fluorescent Lamp Ballast: General requirements for fluorescent ballasts are as follows:
 - Type: Solid state electronic, programmed rapid start or step-dim ballast. Instant start ballasts are acceptable for line voltage control with infrequent switching. Use programmed start ballasts in areas controlled by occupancy sensor or with frequent switching.
 - Listing: Listed with UL; certified by lighting ETL; labeled by Certified Ballast Manufacturer Association (CBM)
 - Thermal Rating: Class P; ballast temperature shall not exceed 25°C (77°F) over 40°C (104°F) ambient.
 - Operating Frequency: 20 KHz or higher
 - Minimum Ballast Factor: 0.85
 - Sound Rating: Class A per UL 935-84
 - RFI/EMI: Comply with FCC regulation Part 18
 - Total Harmonic Distortion: Less than 10%
 - Transient Voltage Protection: Comply with IEEE C62.41.1 and IEEE C62.41.2
 - Dimming: Dimmable electronic ballast shall be capable of dimming light output to 10% of full light output.
 - Lighting Regulation: $\pm 10\%$ lighting output variation with $\pm 10\%$ nominal input voltage variation
 - Warranty: Minimum five years
 - Contain no polychlorinated biphenyl (PCB)

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- Fluorescent ballast and LED Driver types must be coordinated with specified controls. Only electronic ballasts shall be utilized, and LED drivers compliant with IEEE guidelines shall be specified to prevent flicker.
- Though not required by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) organization's accreditation, all lighting fixtures may require emergency backup at the discretion of animal program.
- Coordinate animal research-related lighting issues such as photo-toxicity in housed animals to adjust lighting levels to facilitate research needs.
- Occupancy sensors in animal research facilities shall have no ultrasonic sound emissions in order to limit disruptions to research animals.
- Provide an additional single lamp lighting fixture controlled by a local switch for out-of-diurnal-cycle entry at the discretion of veterinary program. This fixture shall have a red (or possibly other color) sleeve or filmed lens for the lamp at the discretion of veterinary program.
- Provide one local override switch outside each holding room door to turn on the lamp(s) associated with the "on" cycle, plus remaining fixture lamps to achieve an 810 lux (75 fc) level within each room during the caretaker cycle.
- Provide a programmable diurnal lighting cycle, which typically provides 12 hours "on" cycle and 12 hours "off" cycle, allowing adjustment of either cycle duration or providing for multiple cycles in a single day at user discretion.
- For both "on" and "off" lighting operation scenarios, an override switch shall circumvent the programmable lighting panel controls diurnal cycling for a user adjustable period of between 0–60 minutes, and then have the programmable lighting control revert back to its normal diurnal cycle as previously programmed.
- Lighting fixtures and control for the animal holding room that require flexibility to handle multiple types of species shall utilize dimmable fixtures and dimming controls
- Provide a terminal for user control and adjustment of lighting cycles within the animal research supervisor's office, or at another location within the animal research holding area as directed by the user.
- Provide a programmable diurnal lighting cycle, which typically provides 12 hours "on" cycle and 12 hours "off" cycle, allowing adjustment of either cycle duration or providing for multiple cycles in a single day at user discretion.
- Though not required by AAALAC accreditation, all animal holding rooms may require monitoring, reporting and alarming on lighting cycle function within each room at the discretion of the animal program. Reporting requirements may include proofing of diurnal cycle and illumination levels.

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 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.