



## Tradeline Publications: Lovelace Respiratory Research Institute Commissions ABSL-3 Lab

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Orinda, California

Lovelace Respiratory Research Institute (LRRI), a private biomedical research organization in Albuquerque, NM, recently opened an advanced 9,500-sf ABSL-3 aerobiology laboratory after an intensive commissioning and validation process. The facility is used to study aerosolized pathogens on the CDC's Select Agent List and for vaccine efficacy testing. Built on a strict 17-month timeline, the facility is subject to exacting regulatory requirements. To ensure that the facility would operate as expected and meet all safety requirements, the organization applied an intensive inspection and testing process dubbed, "CVQx" (commissioning, validation, and qualification).

"We in the biocontainment industry have a responsibility to our communities, co-workers, and employees to develop facilities that are safe and reliable over the long term. Engaging the CVQx plan helped toward achieving this objective and to assure that the lab was built on time and on budget to the highest possible standards," says John Lopez, facilities director for LRRI.

LRRI is the only private organization in the country exclusively dedicated to the study of respiratory disease. The organization's ABSL-3 inhalation research facility, which opened in 2005, will study exposure to a variety of airborne pathogens and toxins, including those potentially used in biological terrorism. Due to the nature of the research, the facility must have solid and liquid waste decontamination, HEPA filtration of all incoming and out-going air, and completely redundant electrical, HVAC, and monitoring systems.

The facility uses an array of sophisticated equipment to simulate natural inhalation exposure. The majority of the building is BSL-3 rated and, since pathogens are aerosolized, personnel must wear individual breathing apparatus. Because the facility does work involving multiple select agents and animal species, and vaccine efficacy testing, it is subject to rigorous regulatory standards including CDC, USDA and FDA. These regulations stipulate that the performance of core facility elements be thoroughly inspected and tested prior to operation, and that all test results be documented.

To achieve this, a core team of project stakeholders—including representatives from the general contractor, architecture-engineer, vendors, subcontractors, and LRRI

facility staff—was forged to execute the CVQx plan. Team members were carefully selected early in the planning process.

"The CVQx team needs to be as small as possible, and have someone with the authority to make final decisions, or things will get bogged down and the project won't be delivered on time," says Lopez.

### Terms to Build On

*Commissioning* is the process of ensuring that a building functions according to design specifications. It is an essential part of containment facility construction. Commissioning actions—many of which are prescribed by government regulations and industry standards—can be handled by in-house staff, the architecture firm responsible for design, or a third-party expert.

The term *validation*, in the CVQx model, refers to validating the functionality of systems like computerized inventory, access tracking, and how digital records are secured.

"There are very specific procedures for managing electronic data in an FDA-regulated facility. If your records are all computerized, it adds a whole level of validation requirements. You have to be able to prove that the data are accurate, complete, and have not been modified. Security is paramount in that particular area," says Lopez.

*Qualification* means confirming that the basic operational elements and subcontractors are qualified to meet the regulatory demands of the facility. This includes things like caging, network, and communications systems.

### Engaging the Process

Identifying who will conduct the specific inspections and tests is an important step in CVQx implementation. Potential external resources include specialized system technicians, vendor subcontractors, and industry consultants. In-house resources include information services, facility operations staff, researchers, and quality assurance personnel. The optimum situation is a blend of both internal and external resources, but Lopez points out that finding qualified vendors can be a challenge.

“Thoroughly documented inspection and testing are not necessarily strong capabilities of many contractors. If external resources are used, careful evaluation of their commissioning experience is important,” says Lopez.

In order to maintain a high level of control over significant project details, the team handled facility commissioning internally, with the selective addition of specialized external support. The decision to perform most CVQx procedures in-house was driven by a number of factors including lack of qualified vendors and contractors, the greater flexibility in coordinating testing with internal personnel, the desire to maximize the value of the inspection and testing activities to train operating and maintenance personnel, and the necessity to perform ongoing commissioning and recommissioning.

LRRI staff wrote and executed all test scripts. In situations where external resources were used, internal personnel were assigned to provide oversight and gain procedural knowledge that contributed to the sustainability of ongoing operations. There were several areas where the team deemed it crucial to have in-house personnel actively involved in the testing, including HVAC controls, effluent decontamination, and sterilizers. This substantially improved knowledge retention and made for a smoother transition from construction to operation.

“We considered it mandatory for our most knowledgeable instrumentation and controls technician to be involved in the inspection and testing of the HVAC control system. The contractor can achieve basic functionality, but higher levels of performance are best achieved by the person responsible for ongoing operations,” Lopez says.

## **Risk Assessment**

Conducting a thorough commissioning and validation process can be an expensive, time consuming operation. To control costs and prevent pre-commission occupancy, the team applied the principles of risk assessment in determining which issues to address.

“A functional CVQx plan must be based on sound risk assessment principles. Otherwise, cost and schedule can get out of hand. You have to look at each project element and activity and decide if it’s warranted relative to the effort, and risk,” Lopez says.

The CVQx plan constituted 7 percent of total project cost, with more than 800 components tested at a rate of approximately \$650 a component.

“Obviously, when you go through this kind of process at this level, especially in terms of FDA compliance, it raises the bar considerably,” Lopez says.

## **Defining Scope**

The team faced a wide range of considerations when choosing when and where to apply the CVQx procedure.

It was important to decide early in the process what elements were going to be analyzed so the team could determine the best sequence and methodology for testing them.

“The fundamental performance objective was containment, environmental control, sterilization and decontamination, security, communications and alarm response and notification, so these established our initial scope. We focused on meeting CDC, USDA and FDA requirements because there were a lot of things we could do in this regard early in the process,” says Lopez.

The CVQx team used a pyramid-based model to identify the potential actions that might be executed for each component and system of the project. At the base of the model are fundamental procedures like pressure tests and physical material and installation inspections. Progressively moving up, the team looks at things like vendor qualification, factory inspections, performance tests, delivery inspections, and equipment calibration.

“Calibration can be a problem for contractors and it’s an important issue because if the test equipment and system components, such as differential pressure sensors, aren’t calibrated properly, then everything that happens afterward is suspect,” he says.

At the top of the CVQx pyramid is the functional testing of integrated operational elements like HVAC balance, biosafety cabinets, and decontamination systems. These systems were tested as early in the process as possible to identify and correct problems in anticipation of subsequent testing. In one case, the team tested the facility’s effluent decontamination system by pumping wastewater from another animal and laboratory facility through it.

“We could have waited to test that until we had waste coming from the building, but if there was a problem, it would have been a really big problem. So we tested the system by pumping waste through it from a comparable non-contaminated source. By the time we went operational, we had already run 160 batches through,” Lopez says.

## **Testing and Adjusting**

Functional tests are intended to ensure that design requirements are met and to demonstrate the real life performance of systems and equipment once the building is operational. Functional tests were conducted to test integrated performance looking at the impact one system has on another, such as the impact of different HVAC systems; to test performance during abnormal operating conditions such as loss of facility power; to simulate operating conditions during normal operating and maintenance such as isolating rooms for decontamination; and lastly, to determine the maximum capacity of systems such as the effluent decontamination system. LRRI devel-

oped most of the forms and checklists used in the testing process including instructions for documenting results, failures, and corrective actions.

“Functional testing is really the ultimate performance measure. Until you test all the integrated systems and resolve any deficiencies, you don’t have an acceptable facility,” Lopez says.

More than 250 inspections and tests were conducted as part of the CVQx process. This resulted in the identification of 113 deficiencies that needed to be resolved. Some of these were the result of improperly executed tests, some due to contractor installation errors, and some were design issues. When a deficiency was discovered, it was resolved and then re-tested with detailed documentation of every step logged in a database.

“Resolving deficiencies creates great training opportunities. We learned something from every one of those deficiencies,” says Lopez.

Deficiencies were identified with the building automation system and with backup battery systems during simulated power outages; there were conflicts with doors and hardware as they related to directional airflow; and there were conflicts between systems identified during integrated functional testing. Each of these issues were identified in the CVQx process, resolved, and re-tested prior to facility occupancy.

“It is difficult to predict all of the interrelations from a design perspective and foresee the issues that come up when systems react in the real world. This is why a thorough commissioning and validation plan is essential for the safe operation of BSL facilities,” he says.

## Biography

John Lopez is the major projects manager for the Lovelace Respiratory Research Institute in Albuquerque, N.M. He has been designing, building, and managing

research facilities for more than 30 years. Lopez has been trained in the design, operation, and safety principles of biocontainment facilities, including agent-specific training. In the past 10 years, he has been responsible for the design, commissioning, and operations of 11 BSL-2 and BSL-3 facilities.

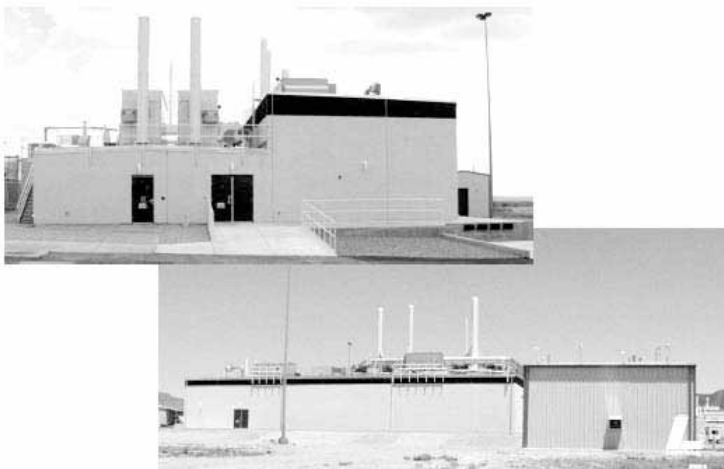
This report is based on a presentation given by John Lopez at Tradeline’s *International Conference on Biocontainment Facilities* in March 2006.

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## Project Information

- Size: 9,500 sf
- Cost: \$7.2 million
- Time: 17 months
- Building Function: aerobiology, virology, microbiology, necropsy, small animal and primate vivarium.
- Architect: Lord, Aeck & Sargent, Atlanta
- Autoclave: Getinge USA Inc., Rochester, New York
- Biosafety Cabinets: NuAire, Plymouth, Minnesota
- Fire Protection Engineer: CCRD, Houston, Texas
- General Contractor: Gerald Martin, Ltd., Albuquerque, New Mexico
- MEP Engineering: CCRD, Houston, Texas
- Structural Engineer: Waller-Davis Associates Inc., Norcross, Georgia
- Waste Reduction System: WR<sup>2</sup> Waste Reduction Inc., Indianapolis, Indiana

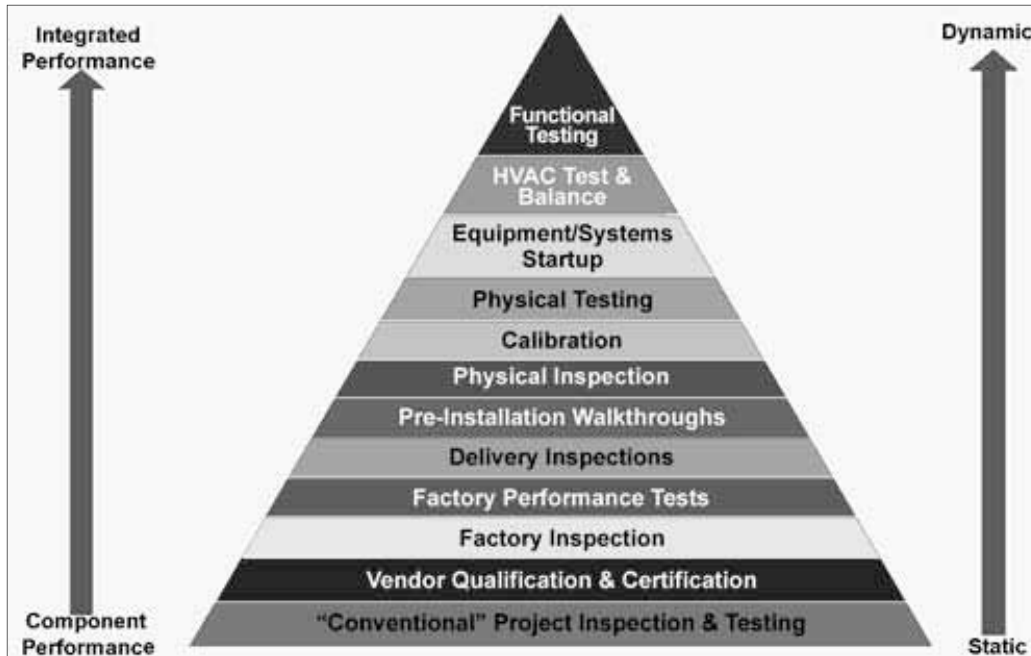


**Figure 1**

The Lovelace Respiratory Research Institute’s new 9,500-sf aerobiology research laboratory was finished in 17 months at a cost of \$7.2 million. The state-of-the-art laboratory will be used to study aerosolized pathogens potentially used in biological terrorism and for vaccine efficacy testing. The majority of the building is BSL-3 rated and features specialized research equipment designed to simulate varying levels of pathogenic exposure. Because the building handles multiple select agents and animal species and is used for vaccine research it is subject to intensive regulatory requirements and federal oversight. (Photo courtesy of Lovelace Respiratory Research Institute.)

**Figure 2**

The CVQx team used a pyramid-based model to identify the potential actions that might be executed for each component and system of the project. At the base are vendor qualifications, static component tests and factory inspections. Each progressive level of the pyramid depends on success of the prior levels. At the top of the pyramid are the dynamic, functional operational tests of active systems. Each step of the process is thoroughly documented at all levels. (Image courtesy of Lovelace Respiratory Research Institute.)



**From EPA's Office of Pesticide Programs 12/19/06  
[www.epa.gov/pesticides](http://www.epa.gov/pesticides)**

In This Update:

Web Page Available on the Prevention of Foot Spa-Associated Nail Infections

To help reduce the potential for skin infections associated with use of whirlpool foot baths in nail salons, EPA, jointly with the Centers for Disease Control and Prevention, now has information on its Web site about this issue. This information will inform the public about steps they can take to protect themselves from infections. It also provides guidance to nail salon owners and operators about proper disinfecting procedures. This fact sheet highlights clear instructions on proper use of disinfection products and a set of recommended cleaning and disinfecting procedures for salon owners and workers to follow. A model product label is included on the web site to help guide nail salon workers in the proper use of the disinfectant; it also highlights the importance of reading and following label directions.

The most important steps salon patrons can take to reduce the likelihood of an infection are:

- 1) Avoid shaving during the 24 hours before receiving a pedicure and do not have a pedicure if you have an open cut on your feet or lower leg area; this has been linked to skin infections.
- 2) Become familiar with a salon's cleaning and disinfecting routine. The consumer should not be afraid to ask what steps are taken to make the foot bath safe. Specifically,
  - a) An EPA-registered hospital disinfectant should be used after each customer.
  - b) All parts of the foot bath should be disinfected, including the filter screen, piping and jets that cannot be seen, after each customer. The disinfectant should be run through the foot bath system according to product label directions (typically, for about 10 minutes).

The web page can be found at [www.epa.gov/pesticides/factsheets/pedicure.htm](http://www.epa.gov/pesticides/factsheets/pedicure.htm)