

Steve Sisolak  
Governor

Richard Whitley, MS  
Director



**DEPARTMENT OF  
HEALTH AND HUMAN SERVICES**  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
*Helping people. It's who we are and what we do.*



Lisa Sherych  
Administrator

Ihsan Azzam,  
Ph.D., M.D.  
Chief Medical Officer

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## Variance #718

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## NOTICE OF PUBLIC HEARING

### VITALANT IS REQUESTING A VARIANCE, #718, FROM THE NEVADA STATE BOARD OF HEALTH REGULATIONS.

NOTICE IS HEREBY GIVEN that the VITALANT, a nonprofit organization, has requested a variance from Nevada Administrative Code (NAC) 652.370(2).

A public hearing will be conducted on September 3<sup>rd</sup>, 2021 at 9:00 am, by the Nevada State Board of Health to consider this request. This meeting will be held via online conference and at physical locations.

#### Meeting Locations:

- **Red Rock Conference Room,**  
Southern Nevada Health District,  
280 S. Decatur, Las Vegas, NV 89107
- **4150 Technology Way; Conference Room 303**  
4150 Technology Way, Third Floor  
Carson City, NV 89706

#### Join from computer using the meeting link:

<https://zoom.us/j/99339558897?pwd=dis1akphUFNIS1pTUE9BQTBINFRNUT09>

Meeting ID: 993 3955 8897

Passcode: 640932

One tap mobile: +12532158782,,99339558897,,,,\*640932# US

#### Join by Phone:

+1 669 900 9128

Meeting ID: 993 3955 8897

Passcode: 640932

**VITALANT, a nonprofit organization, is requesting a variance from NAC 652.370(2), which states:**

**NAC 652.370 Director: Availability and presence; prohibition against serving more than five laboratories; exception. (NRS 439.200, 652.123, 652.130)**

1. A director shall be available to the personnel of a laboratory, in person or by telephone or other electronic means, for any necessary consultation.

2. The director must be on the premises of the laboratory at least once each month. If the director is absent from the laboratory for 1 month or more, the director shall provide a licensed substitute to serve in his or her place, unless the laboratory is in a rural area and the Division determines that a substitute is not necessary.

3. Except as otherwise provided in this subsection, a natural person shall not simultaneously serve as director of more than five laboratories. A natural person may simultaneously serve as director of more than five laboratories if the laboratories are registered under one certificate pursuant to subsection 2 of [NAC 652.180](#).

[Bd. of Health, Medical Laboratories Reg. §§ 4.2-4.2.2.4, eff. 8-5-74] — (NAC A 10-17-86; 10-22-93; R133-96, 4-17-98; R104-13, 3-28-2014)

**The authority of the State Board of Health to consider and grant a variance from the requirements of a regulation is set forth at NRS 439.200 and NAC 439.200 – 439.280.**

Persons wishing to comment upon the proposed variance may appear at the scheduled public hearing or may submit written testimony at least five days before the scheduled hearing to:

Secretary, State Board of Health  
Division of Public and Behavioral Health  
4150 Technology Way, Suite 300  
Carson City, NV 89706

Anyone wishing to testify for more than five minutes on the proposed variance must petition the Board of Health at the above address. Petitions shall contain the following: 1) a concise statement of the subject(s) on which the petitioner will present testimony; 2) the estimated time for the petitioner's presentation.

This notice has also been posted at the following locations:

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH, 4150 TECHNOLOGY WAY, CARSON CITY, NV

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH WEBSITE:

<http://dpbh.nv.gov/Boards/BOH/Meetings/Meetings/>

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August 5, 2021

**MEMORANDUM:**

To: Jon Pennell, DVM, Chairperson  
State Board of Health

From: Lisa Sherych, Administrator  
Division of Public and Behavioral Health

RE: Vitalant-Las Vegas

**Subject:** Case #718: Vitalant-Las Vegas's request for variance to Nevada Administrative Code (NAC) 652.652.370, *Director: Availability and presence;*

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**Staff Review**

NAC 652.370(2) states, "The director must be on the premises of the laboratory at least once each month. If the director is absent from the laboratory for 1 month or more, the director shall provide a licensed substitute to serve in his or her place, unless the laboratory is in a rural area and the Division determines that a substitute is not necessary."

Vitalant-Las Vegas is a laboratory located in Las Vegas that is a source for blood and blood products to health care facilities in the State of Nevada in which Vitalant has a contract. Vitalant also is a resource for specialized antibody testing, antibody identification and compatibility testing to contracted facilities.

Vitalant-Las Vegas has requested a variance of NAC 652.370(2) which requires a laboratory director be present on site of the laboratory, at least one time a month.

**Intent of the regulation:**

The intent of NAC 652.370(2) is to ensure that the laboratory director is engaged in the operations of the laboratory and ensures the director is available for on-site consultation with employees due to the complexities of the laboratory services offered. The laboratory director can only fully understand if the laboratory is in compliance with State regulations and statutes and federal requirements, if the laboratory director is on-site at the laboratory at least once a month.

**Exceptional and Undue Hardship:**

Vitalant-Las Vegas has stated that this regulation is unduly burdensome and imposes unnecessary hardship for Vitalant; due to the time and travel cost associated with complying with NAC 652.370(2), instead of using telephone or electronic off-site support for the laboratory.

Vitalant states that the travel impact for the round-trip flight would cost Vitalant \$3600-\$4800 annually. The laboratory also indicates that at least 3 times each month the laboratory director would not be available for consultation.

**Degree of risk to health and safety:**

Vitalant describes that the degree of risk to health and safety would be minimal; due to the ability of the laboratory director to meet with the laboratory monthly by electronic means with on-site visits to be conducted quarterly unless more frequent visits are required to address specific issues. In addition, Vitalant states that in combination with regular telephone/electronic support and scheduled meetings, it would ensure laboratory director support of the laboratory. No additional explanation of support was provided by the applicant.

**Discussion:**

Along with other requirements, NAC 439.240 indicates variances will only be granted if the Board finds that circumstances or conditions, make compliance with the regulation unduly burdensome and cause a hardship to and abridge a substantial property right of the applicant. In addition, granting the variance must not be detrimental or pose a danger to public health and safety.

The applicant's indicated cost of travel annually (\$4,800) does not present as unduly burdensome, nor present as substantial abridgement of the applicant's property right. NAC 652.370(2) requires minimal on-site presence to ensure compliance with regulatory requirements that have been established to maintain safety of the public through obtaining and reporting accurate results. According to documents submitted by the laboratory, a change of director occurred at Vitalant-Las Vegas on September 9, 2020. An inspection of the laboratory occurred on June 3, 2021 and identified deficiencies concerning:

- a. Laboratory proficiency testing revealed that ungraded proficiency test results were not properly evaluated and documented according to the laboratory director policy and procedure.
- b. There were laboratory assistants that were working in the laboratory with no State of Nevada laboratory personnel license. In addition, some laboratory assistants were working in the laboratory, after their laboratory personnel licenses had expired.
- c. Vitalant -Las Vegas requested a compliance agreement for the laboratory director to be on-site at least once a quarter and to meet with the laboratory once a month by phone or electronic means. This compliance agreement was signed by the laboratory director of Vitalant-Las Vegas on April 3, 2020, put into effect on April 6, 2020, then subsequently approved by the Board of Health at their June 2020 meeting. Vitalant-Las Vegas was not in compliance with the agreement, as the laboratory director failed to be on-site of the laboratory from September 2020 through June 2021.

Choosing a laboratory director from another state is a business decision that Vitalant made and this variance is related to that choice. However, there are many qualified State Licensed laboratory directors in the Las Vegas area.

**Public comment received:**

None.

**Staff recommendation:**

Staff recommends that the Board of Health deny Vitalant-Las Vegas request for a variance to NAC 652.370(2), based on the applicant not meeting the burden of proof for the criteria identified in NAC 439.240.

**Presenter:**

Bradley Waples, Acting Manager Medical Laboratory Services, Bureau of Healthcare Quality and Compliance



6210 East Oak Street  
Scottsdale, AZ 85257

p 800.288.2199  
f 480.675.5766  
[vitalant.org](http://vitalant.org)

July 14, 2021

Lisa Sherych, Administrator  
Division of Public and Behavioral Health  
4150 Technology Way, Suite 300  
Carson City, NV 89706

Ms. Sherych:

Vitalant is requesting a variance to **NAC 652.370(2)** which requires the laboratory director to be on the premises of the laboratory at least once each month. In lieu of this requirement, we are proposing that the Vitalant laboratory director be allowed to meet with the facility staff at least once a month via phone or other electronic means with onsite visits occurring quarterly, rather than visiting the premises of the laboratory at least once per month. This request is being made for our Nevada Licensed Laboratory located at 6930 W Charleston Blvd, Las Vegas, NV 89117 (License 1505-LIC-16).

Vitalant is a nonprofit organization that collects blood from volunteer donors and provides blood products and related services across the United States. As the laboratory director for this location, I am based out of San Francisco, California and have responsibilities as a medical director for Vitalant across Southern Nevada and San Francisco Bay Area/Central California.

We believe the following information provides the necessary information required for the Application for Variance.

1. Exceptional and undue hardship:

Regulation **NAC 652.370(2)** requiring the medical director to be on the premises of the laboratory at least once each month is unduly burdensome and imposes unnecessary hardship for Vitalant. Travel cost and time associated with NAC 652.370(2) are disproportionate to the operational need for such a requirement with existing regular electronic and telephonic offsite support.

Travel impact: roundtrip flight= approximately \$300-400 per month for a total of \$3600-4800/annually. This does not account for at least 3 hours travel time per month in which the director may not be available for consultation to this or other facilities.

2. Variance, if granted would not cause substantial detriment to public welfare:

Testing is performed by Nevada licensed personnel. In addition to inspection by the State of Nevada, this facility is also licensed and inspected by FDA and holds a Certificate of Accreditation with AABB who ensures CLIA requirements are being met biennially. Vitalant has a large operational footprint with much of the medical, operational, and quality leadership operating remotely and has a robust history of offsite laboratory/medical director support without safety or quality concerns. All Vitalant facilities in Nevada and the service area I cover are under the same leadership and use the same Blood Establishment Computer Systems, standard operating procedures, and

policies across our national organization. Vitalant has invested in information technology solutions for remote conferencing and virtual team support.

Laboratory/medical directors interface regularly with Nevada hospitals and Vitalant facilities with staff having 24/7 direct access to the Laboratory Director or designees who serve as the Laboratory Director at other Vitalant facilities working within the same geographic region with the same leadership as discussed above. The net effect is that I have regular interactions with the leadership team over this facility, as well as with laboratory staff who perform moderate and high complexity testing. Granting a variance to NAC 650.370(2), therefore, would not be detrimental or pose a danger to public health and safety.

3. Variance would not impair substantially the purpose of the regulation:

Vitalant is seeking a variance to NAC 652.370(2) that would allow the laboratory director to meet with the facility at least once a month via phone or other electronic means with onsite visits occurring quarterly unless more frequent visits are required to address specific issues. This, in combination with regular telephone/electronic support and scheduled operational meetings ensures appropriate laboratory director support of this facility and is consistent with how laboratory directors in other parts of our organization interact with the remote facilities they support. The purpose of the regulation is to ensure continued safety and quality of laboratory operations. Vitalant can meet this standard and optimally support Nevada donors, patients, and facilities through the proposed variance.

If you need any additional information regarding this variance, please feel free to contact me at [sshaikh@vitalant.org](mailto:sshaikh@vitalant.org) or (415) 653-4114 or Tina Chanez, Director Regulatory Compliance at [reglicensing@vitalant.org](mailto:reglicensing@vitalant.org) or (480) 675-5518.

Respectfully submitted,

*Salima Shaikh MD*

Salima Shaikh, MD



NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

Please check the appropriate box that pertains to the NAC for which you are requesting a variance.

Division Administration  
(NAC 439, 441A, 452, 453A, & 629)

Health Care Quality & Compliance  
(NAC 449, 457, 459 & 652)

Child, Family & Community Wellness  
(NAC 392, 394, 432A, 439, 441A, & 442)

Health Statistics, Planning,  
Epidemiology and Response  
(NAC 440,450B, 452, 453, 453A, & 695C)

Public Health & Clinical Services  
(NAC 211, 444, 446, 447, 583, & 585)

Date: July 14, 2021

Name of Applicant: Salima Shaikh (Vitalant)

Phone: 415-653-4114

Mailing Address: 6930 W Charleston Blvd

City: Las Vegas

State: NV

Zip: 89117

We do hereby apply for a variance to \_\_\_\_\_ of the Nevada  
chapter/section NAC 652.370(2)  
Administrative Code (NAC). (For example: NAC 449.204)

Title of section in  
question:

Director: Availability and presence; prohibition against serving more than five laboratories; exception.

Statement of existing or proposed conditions in violation of the NAC:

Use of monthly standing remote meetings plus quarterly on-site visits to document director availability and presence.

NAC currently states in (2) "The director must be on the premises of the laboratory at least once each month."

Please see attached letter for rationale and additional information.

NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

Date of initial operation (if existing): \_\_\_\_\_

**ATTENTION: Please read this section closely. Your request for variance will be examined against these criteria:**

Any person who, because of unique circumstances, is unduly burdened by a regulation of the State Board of Health and thereby suffers a hardship and the abridgement of a substantial property right may apply for a variance from a regulation. (NAC 439.200(1))

1. The State Board of Health will grant a variance from a regulation only if it finds from the evidence presented at the hearing that:
  - (a) There are circumstances or conditions which:
    - (1) Are unique to the applicant;
    - (2) Do not generally affect other persons subject to the regulation;
    - (3) Make compliance with the regulation unduly burdensome; and
    - (4) Cause a hardship to and abridge a substantial property right of the applicant; and
  - (b) Granting the variance:
    - (1) Is necessary to render substantial justice to the applicant and enable him to preserve and enjoy his property; and
    - (2) Will not be detrimental or pose a danger to public health and safety.
2. Whenever an applicant for a variance alleges that he suffers or will suffer economic hardship by complying with the regulation, he must submit evidence demonstrating the costs of his compliance with the regulation. The Board will consider the evidence and determine whether those costs are unreasonable. (NAC 439.240)

**Therefore, it is important for your variance request to be as complete as possible. It is your responsibility to attach documentation supportive of your variance request.**

Statement of degree of risk of health

Testing at this facility is performed by Nevada licensed personnel.

In addition to the state of Nevada, this facility is also inspected by FDA and AABB. There have not been any significant adverse events (i.e. significant transfusion reactions, patient death, etc.) related to testing performed at this facility. The laboratory director is routinely available by phone for consultation.

Therefore, we do not believe there is any greater risk of health to patients should the variance be granted.

NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

**Please state in detail the circumstances or conditions which demonstrate that:**

1. An exceptional and undue hardship results from a strict application of the Regulation:

Please refer to attached letter for explanation and rationale.

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2. The variance, if granted, would not:
  - A. Cause substantial detriment to the public welfare.

Please refer to attached letter and explanation.

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- B. Impair substantially the purpose of the regulation from which the application seeks a variance.

Please refer to attached letter and explanation.

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The bureau may require the following supporting documents to be submitted with and as a part of this application:

1. Legal description of property concerned
2. General area identification map

NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

- \_ 3. Plat map showing locations of all pertinent items and appurtenances
- \_ 4. Well log (if applicable)
- \_ 5. Applicable lab reports
- \_ 6. Applicable engineering or construction/remodeling information
- \_ 7. Other items (see following pages)

This application must be accompanied by evidence demonstrating the costs of your compliance with regulations or specific statutory standards. Your request will be placed on the Board of Health agenda 40 days or more after receipt in this office if accompanied by the required fee (NAC 439.210). The application and supporting documentation will form the basis for the Division of Public and Behavioral Health staff report and recommendation(s) to the Board. Failure to respond to the above statements may cause the Board to deny consideration of the application at the requested Board meeting.

Please schedule this hearing during:

The next regularly scheduled Board of Health meeting, regardless of location.

The next scheduled meeting in Carson City.

The next scheduled meeting in Las Vegas.

Signature: Salima Shaikh MD

Printed Name: Salima Shaikh

Title: Medical Officer, West and Southwest Divisions

Date: July 13, 2021

NEVADA STATE BOARD OF HEALTH  
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
4150 Technology Way, Suite 300  
CARSON CITY, NV 89706

**APPLICATION FOR VARIANCE**

**PLEASE SUBMIT YOUR APPLICATION FOR VARIANCE BY USING  
ANY OF THE FOLLOWING METHODS:**

**MAIL TO:**

Lisa Sherych, Administrator  
Division of Public and Behavioral Health  
4150 Technology Way, Suite 300  
Carson City, NV 89706

**FAX:**

775-687-7570

**EMAIL:**

[DPBH@health.nv.gov](mailto:DPBH@health.nv.gov)

**Before the Nevada State Board of Health**

**September 3, 2021**

In the matter of: Vitalant-Las Vegas

State laboratory license number: 1505 LIC

Variance request: Case #718

**Findings of Fact**

1. The division of Public and Behavioral Health has received a request for variance from Nevada Administrative Code (NAC) 652.370(2).

2. NAC 652.370(2) states:

The director must be on the premises of the laboratory at least once each month. If the director is absent from the laboratory for 1 month or more, the director shall provide a licensed substitute to serve in his or her place, unless the laboratory is in a rural area and the Division determines that a substitute is not necessary.

3. The intent of the regulation NAC 652.370(2) to ensure that the laboratory director is engaged in the operations of the laboratory and ensures the director is available for on-site consultation with employees due to the complexities of the laboratory services offered. The laboratory director can only fully understand if the laboratory is in compliance with State regulations and statutes and federal requirements if the laboratory director is on-site at the laboratory at least once a month.

4. The laboratory services that are provided by Vitalant-Las Vegas in the State of Nevada are:

- a). Therapeutic and non-therapeutic blood donation.
- b). Blood and blood product processing and distribution.
- c). Laboratory testing in the area of Bacteriology.
- d). Laboratory testing in the area of Hematology.
- e). Laboratory testing in the area of Immunohematology which includes ABO/Rh testing, antibody identification for transfusion and non-transfusion purposes, antibody identification and compatibility testing.

5. Along with other requirements, NAC 439.240 indicates variances will only be granted if the Board finds that circumstances or conditions, make compliance with the regulation unduly burdensome and cause a hardship to and abridge a substantial property right of the applicant. In addition, granting the variance must not be detrimental or pose a danger to public health and safety.

The applicant's indicated cost of travel annually (\$4,800) does not present as unduly burdensome, nor present as substantial abridgement of the applicant's property right. NAC 652.370(2) requires minimal on-site presence to ensure compliance with regulatory requirements that have been established to maintain safety of the public through obtaining and reporting accurate results. According to documents submitted by the laboratory, a change of director occurred at Vitalant-Las Vegas on September 9, 2020. An inspection of the laboratory occurred on June 3, 2021 and identified deficiencies concerning:

- a. Laboratory proficiency testing revealed that ungraded proficiency test results were not properly evaluated and documented according to the laboratory director policy and procedure.
- b. There were laboratory assistants that were working in the laboratory with no State of Nevada laboratory personnel license. In addition, some laboratory assistants were working in the laboratory, after their laboratory personnel licenses had expired.
- c. Vitalant -Las Vegas requested a compliance agreement for the laboratory director to be on-site at least once a quarter and to meet with the laboratory once a month by phone or electronic means. This compliance agreement was signed by the laboratory director of Vitalant-Las Vegas on April 3, 2020, put into effect on April 6, 2020, then subsequently approved by the Board of Health at their June 2020 meeting. Vitalant-Las Vegas was not in compliance with the agreement, as the laboratory director failed to be on-site of the laboratory from September 2020 through June 2021.

Choosing a laboratory director from another state is a business decision that Vitalant made, and this variance is related to that choice. However, there are many qualified State Licensed laboratory directors in the Las Vegas area.

The importance of the services that Vitalant-Las Vegas provides in the State of Nevada in the form of supplying critical blood and blood products and a resource for Immunohematology testing is acknowledged. The Division of Public and Behavioral Health has made the attempt to work with Vitalant-Las Vegas to create a compliance agreement during the COVID pandemic that would require monthly director virtual visits and quarterly director on-site visits. In trying to work together with Vitalant-Las Vegas and securing a compliance agreement, the laboratory director did not meet the requirements of the compliance agreement.

Given the information above and understanding the importance of having a laboratory director on-site at least once a month, staff recommend that the variance request for NAC 652.370(2) be denied.

### **Conclusions of Law**

1. This matter is properly before the Nevada State Board of Health pursuant to the Nevada Revised Statute (NRS) 439.200 and determination of the matter on the merits is properly within the subject matter jurisdiction of the board.
2. NRS 439.200 provides:

The State Board of Health may grant a variance from the requirements of a regulation if it finds that:

- (a) Strict application of that regulation would result in exceptional and undue hardship to the person requesting the variance; and
  - (b) The variance, if granted would not:
    - (1) Cause substantial detriment to the public welfare; or
    - (2) Impair substantially the purpose of the regulation.
3. The Board finds that strict application would result in an exceptional and undue hardship.
4. The Board finds that granting this variance would not impair the purpose of the regulation or cause a substantial detriment to the public welfare.

**Order**

Based upon the foregoing Findings of Fact and Conclusions of Law, and good cause appearing, therefore, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the variance from NAC 652.370(2) is DENIED as presented; specifically, Vitalant-Las Vegas will be required to be in compliance with the regulation requiring a laboratory director to be on the premises of the laboratory at least once a month. The laboratory director will be allowed to meet the requirements of the compliance agreement which was approved by the Board at the June 2020 Board of Health meeting until the terms of the compliance agreement has ended.

DATED this \_\_\_\_\_ day of \_\_\_\_\_, 2021

\_\_\_\_\_  
Jon Pennell, DVM, Chairperson

Nevada State Board of Health



**Certificate of Mailing**

I hereby certify that I am employed by the Department of Health & Human Services, Division of Public and Behavioral Health, and that on the \_\_\_\_\_ day of \_\_\_\_\_, 2021, I served the foregoing FINDINGS OF FACT AND DECISION by mailing a copy thereof to:

Vitalant-Las Vegas

6930 W. Charleston Blvd.

Las Vegas, NV 89117

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