COMMONWEALTH of VIRGINIA

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§50 FAQ 3

Are diagnostic laboratories that conduct routine medical testing and environmental specimen testing for COVID-19 required to operate at Biosafety Level 3 (BSL-3)?

NOTE: The Answer follows a discussion of applicable sections of the ETS and other relevant documents.

Applicable Sections of the ETS

16VAC25-220-10.E provides:

> 16VAC25-220-10. Purpose, scope, and applicability.
> ….
> E. Application of this standard to a place of employment will be based on the **exposure risk level presented by SARS-CoV-2 virus-related and COVID-19 disease-related hazards present or job tasks undertaken by employees** at the place of employment as defined in this standard (i.e., very high, high, medium, and lower risk levels). (Emphasis added).

16VAC25-220-50.B.6, Requirements for hazards or job tasks classified as very high or high exposure risk, provides:

> B. Engineering controls.
> ….
> 6. Employers shall use special precautions associated with Biosafety Level 3 (BSL-3), as defined by the U.S. Department of Health and Human Services [HHS] Publication No. (CDC) 21-1112 **"Biosafety in Microbiological and Biomedical Laboratories" (Dec. 2009),[1] which is hereby incorporated by reference**, when handling specimens from known or suspected to be infected with the SARS-CoV-2 virus patients or persons. (Emphasis added).

[1] https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

16VAC25-220-40.B, Mandatory requirements for all employers, provides:

> 16VAC25-220-40. Mandatory requirements for all employers.
> ….
> B. Exposure assessment and determination, notification requirements, and employee access to exposure and medical records.
>
> 1. Employers shall assess their workplace for hazards and job tasks that can potentially expose employees to the SARS-CoV-2 virus or COVID-19 disease. **Employers shall classify each job task according to the hazards employees are potentially exposed** to and ensure compliance with the applicable sections of this standard for very high, high, medium, or lower risk levels of exposure. Tasks that are similar in nature and expose employees to the same hazard may be grouped for classification purposes. (Emphasis added).

16VAC25-220-30. Definitions, provides:

> ….
> "Very high" exposure risk hazards or job tasks are those in places of employment with high potential for employee exposure to known or suspected sources of the SARS-CoV-2 virus (e.g., laboratory samples) or persons known or suspected to be infected with the SARS-CoV-2 virus, including, but not limited to, during specific medical, postmortem, or laboratory procedures:
>
> 1. **Aerosol-generating procedures** (e.g., intubation, cough induction procedures, bronchoscopies, some dental procedures and exams, or invasive specimen collection) on a patient or person known or suspected to be infected with the SARS-CoV-2 virus;
> 2. **Collecting or handling specimens** from a patient or person known or suspected to be infected with the SARS-CoV-2 virus (e.g., **manipulating cultures** from patients known or suspected to be infected with the SARS-CoV-2 virus).
>
> "High" exposure risk hazards or job tasks are those in places of employment with high potential for employee exposure inside six feet with known or suspected sources of SARS-CoV-2, or with persons known or suspected to be infected with the SARS-CoV-2 virus that are not otherwise classified as very high exposure risk, including, but not limited to:
>
> 1. Healthcare (physical and mental health) delivery and support services provided to a patient known or suspected to be infected with SARS-CoV-2 virus, . . .
> 2. Healthcare (physical and mental health) delivery, care, and support services, . . . provided to a patient, resident or other person known or suspected to be infected with the SARS-CoV-2 virus involving . . . **COVID-19 testing services** . . .
>
> (Emphasis added).

16VAC25-220-10.G.1, Purpose, scope, and applicability, provides.

> ….
> G. 1. To the extent that an employer actually complies with a recommendation contained in CDC guidelines, whether mandatory or non-mandatory, to mitigate SARS-CoV-2 virus and COVID-19 disease related hazards or job tasks addressed by this standard, and provided that the

CDC recommendation provides equivalent or greater protection than provided by a provision of this standard, the employer's actions shall be considered in compliance with this standard. An employer's actual compliance with a recommendation contained in CDC guidelines, whether mandatory or non-mandatory, to mitigate SARS-COV-2 and COVID19 related hazards or job tasks addressed by this standard shall be considered evidence of good faith in any enforcement proceeding related to this standard.

Other Documents

The HHS/Centers for Disease Control and Prevention (CDC) "Biosafety in Microbiological and Biomedical Laboratories", which is incorporated by reference in the ETS,[2] contains a section on dealing with Severe Acute Respiratory Syndrome (SARS) Coronavirus laboratory issues (pages 224-226):

> Severe Acute Respiratory Syndrome (SARS) Coronavirus
>
> SARS is a viral respiratory illness caused by a previously undescribed coronavirus, SARS-associated coronavirus (SARS-CoV) within the family Coronaviridae. SARS was retrospectively recognized in China in November 2002. Over the next few months, the illness spread to other south-east.
> ….
> Laboratory Safety and Containment Recommendations
>
> SARS-CoV may be detected in respiratory, blood, or stool specimens. The exact mode of transmission of SARS-CoV laboratory-acquired infection has not been established, but in clinical settings the primary mode of transmission appears through direct or indirect contact of mucous membranes with infectious respiratory droplets.
>
> In clinical laboratories, whole blood, serum, plasma and urine specimens should be handled using Standard Precautions, which includes use of gloves, gown, mask, and eye protection. Any procedure with the potential to generate aerosols (e.g., vortexing or sonication of specimens in an open tube) should be performed in a BSC. Use sealed centrifuge rotors or gasketed safety carriers for centrifugation. Rotors and safety carriers should be loaded and unloaded in a BSC. Procedures conducted outside a BSC must be performed in a manner that minimizes the risk of personnel exposure and environmental release.
>
> **The following procedures may be conducted in the BSL-2 setting: pathologic examination and processing of formalin-fixed or otherwise inactivated tissues, molecular analysis of extracted nucleic acid preparations, electron microscopic studies with glutaraldehyde-fixed grids, routine examination of bacterial and fungal cultures, routine staining and microscopic analysis of fixed smears, and final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container).** (Emphasis added).

NOTE: SARS-CoV-2 which causes COVID-19 is a SARS Coronavirus.

[2] https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

The CDC "Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)"[3] provides as follows:

> **Routine Diagnostic Testing**
>
> Routine diagnostic testing of specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:
>
> Using automated instruments and analyzers
> Processing initial samples
> Staining and microscopic analysis of fixed smears
> Examination of bacterial cultures
> Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
> Molecular analysis of extracted nucleic acid preparations
> Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)
> Using inactivated specimens, such as specimens in nucleic acid extraction buffer
> Performing electron microscopic studies with glutaraldehyde-fixed grids

Answer

No. To determine the applicability of 16VAC25-220-50.B.6 to a laboratory, regardless of the work being undertaken, the employer must classify job tasks by risk level (very high, high, medium, and lower) based on employee exposures to workplace hazards. See 16VAC25-220-40.B.

In determining the applicability of 16VAC25-220-50.B to a job task, the employer must consider the CDC guidance applicable to the issue.

The classification of job tasks can be activity-specific to identify and mitigate risks associated with a particular job task (e.g., aerosol-generating procedures). Accordingly, for purposes of compliance with 16VAC25-220-50.B, the use of special precautions associated with BSL-3 may only apply to a specific activity and any employee whose job tasks include that activity, not necessarily the entire laboratory and all employees of a laboratory not associated with that job task or risk classification.

Further, the use of special precautions associated with BSL-3 would not absolutely require a laboratory to satisfy every special safety practice, equipment, and facility requirement under BSL-3. Employers may refer to CDC guidance for determining which BSL practices and standards are appropriate to the job task.

Risk Classification

16VAC25-220-50.B.6 only applies to job tasks with very high and high risk classifications.
If the employer determines that there are no job tasks being undertaken by employees during routine medical testing and environmental specimen testing for COVID-19 classified as very high or high, then 16VAC25-220-50.B does not apply.

[3] https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html

Examples of Job Tasks that are not classified as **very high**:

- The ETS definition of very high specifically identifies "aerosol-generating procedures" to which employees are exposed as requiring a very high risk classification. If the employer determines that a laboratory employee does not engage in or is not exposed to aerosol-generating procedures during routine medical testing and environmental specimen testing for COVID-19, then the job task(s) would not be classified as very high.
- The ETS definition of very high specifically identifies "handling" specimens from a patient or person known or suspected to be infected with the SARS-CoV-2 virus. If COVID-19 tests are "handled" in an automated fashion instead of by employees, thereby eliminating direct employee exposure, then the job task(s) would not be classified as very high.

The ETS definition of very high specifically identifies "manipulating cultures from patients known or suspected to be infected with the SARS-CoV-2 virus" to which employees are exposed as requiring a very high risk classification.

If the employer determines that a laboratory employee does not manipulate such cultures during routine medical testing and environmental specimen testing for COVID-19, then the job task(s) would not be classified as very high.

Examples of Job Tasks that are not classified as **high**:

- The ETS definition of high states that high exposure risk hazards or job tasks are those in places of employment with high potential for employee exposure inside six feet with known or suspected sources of SARS-CoV-2. If the employer determines that a laboratory employee does not engage in job tasks with high potential for employee exposure inside six feet with known or suspected sources of SARS-CoV-2 during routine medical testing in a laboratory setting, then the job tasks would not be classified as high.

The ETS definition of high specifically identifies "COVID-19 testing services" "provided to a patient, resident or other person known or suspected to be infected with the SARS-CoV-2 virus."

The use of "COVID-19 testing services" in this definition is intended to apply to those activities performed outside of the laboratory in the clinical environment (e.g., obtaining the specimen from the patient) and does not include the laboratory testing procedures.

CDC Guidance

The employer must consider the CDC guidance in determining exposure risk for any given job task and the associated precautions. HHS/CDC's "Biosafety in Microbiological and Biomedical Laboratories", which is incorporated by reference in the ETS and pre-dates the advent of SARS-CoV-2, specifically provides that the following SARS-CoV handling procedures may be conducted in the BSL-2 setting:

- **Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues,**
- **Molecular analysis of extracted nucleic acid preparations,**

- **Electron microscopic studies with glutaraldehyde-fixed grids,**
- **Routine examination of bacterial and fungal cultures,**
- **Routine staining and microscopic analysis of fixed smears, and**
- **Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container).**

CDC's "Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)" (the "Interim Guidance") provides that routine diagnostic testing of specimens, such as the following activities, can be handled in a BSL-2 laboratory using Standard Precautions:

- Using automated instruments and analyzers
- Processing initial samples
- **Staining and microscopic analysis of fixed smears**
- **Examination of bacterial cultures**
- **Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues**
- **Molecular analysis of extracted nucleic acid preparations**
- **Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)**
- Using inactivated specimens, such as specimens in nucleic acid extraction buffer
- **Performing electron microscopic studies with glutaraldehyde-fixed grids**

NOTE: For ease of comparison, the common elements between the two CDC documents above are highlighted in **bold.**

Based upon this CDC guidance, for any employee performing a job task involving the activities listed above, BSL-3 is not required.

The Interim Guidance also provides that procedures with a high likelihood of generating aerosols or droplets (i.e., aerosol-generating procedures), be done using either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel. Examples of these additional precautions include personal protective equipment (PPE), such as a surgical mask or face shield, or other physical barriers, like a splash shield; centrifuge safety cups; and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel. The Interim Guidance further states that site- and activity-specific biosafety risk assessments be performed to determine if additional biosafety precautions are warranted based on situational needs, such as high testing volumes, and the likelihood to generate infectious droplets and aerosols.

Application to Aerosol-Generating Procedures

CDC Frequently Asked Questions about Coronavirus (COVID-19) for Laboratories (the "FAQs") identify the following laboratory procedures have been associated with the generation of infectious aerosols and droplets (i.e., are aerosol-generating):

- centrifugation,
- **pipetting**,

- vortexing,
- mixing,
- shaking,
- sonicating,
- removing caps,
- decanting liquids,
- preparing smears,
- flaming slides,
- aliquoting and loading specimens,
- loading syringes,
- manipulating needles,
- syringes or sharps,
- aspirating and transferring blood and body fluids,
- subculturing blood culture bottles,
- spilling specimens,
- and cleaning up spills.

Aerosol-generating procedures are classified as very high risk under 16VAC25-220-40.B, accordingly, 16VAC25-220-50.B would apply to any job tasks involving these activities. Some COVID-19 testing platforms use pipetting, which would be classified as very high risk on this basis.

Use of Special Precautions Associated with BSL-3

For any job task for which there is a very high or high risk classification (e.g., for any aerosol-generating procedure) 16VAC25-220-50.B would apply and employers must use special precautions associated with Biosafety Level 3 (BSL-3) **if the job task involves handling specimens from known or suspected to be infected with the SARS-CoV-2 virus patients or persons**.

If the job task or laboratory where the job task occurs do not involve specimens known or suspected to be infected with the SARS-CoV-2 virus, the requirement to use special precautions associated with BSL-3 at 16VAC25-220-50.B.1 does not apply.

CDC Biosafety in Microbiological and Biomedical Laboratories (5th Edition) establishes various standard and special safety practices, equipment, and facility requirements that apply to Biosafety levels.

The standard microbiological practices, special practices, and safety equipment (primary barriers and personal protective equipment) for Biosafety Level 2 (BSL-2) compared to BSL-3 are substantially similar. Accordingly, any laboratory that meets BSL-2 is already using special precautions associated with BSL-3.

COVID-19 testing platforms that include pipetting or other aerosol-generating procedures can be performed in a BSL-2 laboratory using additional precautions associated with BSL-3, including:

- Performing the procedure within a biosafety cabinet (BSC) (Class II or Class III), or other containment device.
- Wearing protective laboratory clothing with a solid-front, such as tie-back or wrap-around gowns, scrub suits, or coveralls.
    - Protective clothing is not worn outside of the laboratory.

- Reusable clothing is decontaminated before being laundered.
- Clothing is changed when contaminated.
- Wear two pairs of gloves when appropriate.

The use of protective clothing with a solid-front is not required. Employers should base selection of protective clothing on applicable standard precautions.

The laboratory would not be required to meet laboratory facilities (secondary barriers) associated with BSL-3 in order to comply with 16VAC25-220-50.B.

Application to Use of Decentralized and Point-of-Care Testing Outside of Laboratories

The CDC Interim Guidance addresses use of point-of-care (POC) tests, such as the Abbott ID NOW mobile molecular device, in testing sites located outside of a laboratory (such as in a health department, physician office, long term care facility, or other congregate setting).

These POC test platforms may involve pipetting or similar procedures, but the Interim Guidance does not classify them as procedures with a high likelihood of generating droplets or aerosols and accordingly, does not indicate the use of a BSC for POC tests. However, the Interim Guidance does instruct that testing sites that operate a POC diagnostic instrument must have a current Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate.

The Interim Guidance also identifies the following special precautions, some of which are associated with BSL-2 and BSL-3:

- Use the instrument in a location associated with a current CLIA certificate.
- Perform a site-specific and activity-specific risk assessment to identify and mitigate safety risks.
- Train staff on the proper use of the instrument and ways to minimize the risk of exposures.
- Follow Standard Precautions when handling clinical specimens, including hand hygiene and the use of PPE, such as laboratory coats or gowns, gloves, and eye protection. If needed, additional precautions can be used, such as a surgical mask or face shield, or other physical barriers, such as a splash shield to work behind.
- When using patient swabs, minimize contamination of the swab stick and wrapper by widely opening the wrapper prior to placing the swab back into the wrapper.
- Change gloves after adding patient specimens to the instrument.
- Decontaminate the instrument after each run by using an EPA-approved disinfectant for SARS-CoV-2.
- Following the manufacturer's recommendations for use, such as dilution, contact time, and safe handling.

The testing site would need to meet the above special precautions associated with BSL-3 in order to comply with 16VAC25-220-50.B.