Regulations for Disease Reporting and Control

Commonwealth of Virginia
State Board of Health
October 2016

Virginia Department of Health
Office of Epidemiology
109 Governor Street
P.O. Box 2448
Richmond, VA 23218

VDH VIRGINIA DEPARTMENT OF HEALTH
Protecting You and Your Environment
www.vdh.virginia.gov

TABLE OF CONTENTS

PART I.

DEFINITIONS

12 VAC 5-90-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Affected area" means any part or the whole of the Commonwealth, which has been identified as where persons reside, or may be located, who are known to have been exposed to or infected with, or who are reasonably suspected to have been exposed to or infected with, a communicable disease of public health threat. "Affected area" shall include, but not be limited to, cities, counties, towns, and subsections of such areas, public and private property, buildings, and other structures.

"Arboviral infection" means a viral illness that is transmitted by a mosquito, tick, or other arthropod. This includes, but is not limited to, chikungunya (CHIK), dengue, eastern equine encephalitis (EEE), LaCrosse encephalitis (LAC), also known as California encephalitis, St. Louis encephalitis (SLE), West Nile virus (WNV), and Zika virus (Zika) infection.

"Board" means the State Board of Health.

"Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas excluding localized basal and squamous cell carcinomas of the skin, except for lesions of the mucous membranes.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

"Child care center" means a child day center, child day program, family day home, family day system, or registered family day home as defined by § 63.2-100 of the *Code of Virginia*, or a similar place providing day care of children by such other name as may be applied.

"Clinic" means any facility, freestanding or associated with a hospital, that provides preventive, diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

"Commissioner" means the State Health Commissioner or his duly designated officer or agent, unless stated in a provision of this chapter that it applies to the State Health Commissioner in his sole discretion.

"Communicable disease" means an illness due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, or arthropod or through the agency of an intermediate host or a vector or through the inanimate environment.

"Communicable disease of public health significance" means an illness caused by a specific or suspected infectious agent that may be transmitted directly or indirectly from one individual to another. This includes but is not limited to infections caused by human immunodeficiency viruses, bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may determine that diseases caused by other pathogens constitute communicable diseases of public health significance.

"Communicable disease of public health threat" means an illness of public health significance, as determined by the State Health Commissioner in accordance with this chapter, caused by a specific or suspected infectious agent that may be reasonably expected or is known to be readily transmitted directly or indirectly from one individual to another and has been found to create a risk of death or significant injury or impairment; this definition shall not, however, be construed to include human immunodeficiency viruses or the tubercle bacilli, unless used as a bioterrorism weapon.

"Companion animal" means, consistent with the provisions of § 3.2-6500 of the *Code of Virginia*, any domestic or feral dog, domestic or feral cat, nonhuman primate, guinea pig, hamster, rabbit not raised for human food or fiber, exotic or native animal, reptile, exotic or native bird, or any feral animal or any animal under the care, custody, or ownership of a person or any animal that is bought, sold, traded, or bartered by any person. Agricultural animals, game species, or any animals regulated under federal law as research animals shall not be considered companion animals for the purpose of this chapter.

"Condition" means any adverse health event, such as a disease, an infection, a syndrome, or as indicated by a procedure (including but not limited to the results of a physical exam, laboratory test, or imaging interpretation) suggesting that an exposure of public health importance has occurred.

"Contact" means a person or animal known to have been in such association with an infected person or animal as to have had an opportunity of acquiring the infection.

"Contact services" means a broad array of services that are offered to persons with infectious diseases and their contacts. Contact services include contact tracing, providing information about current infections, developing risk reduction plans to reduce the chances of future infections, and connecting to appropriate medical care and other services.

"Contact tracing" means the process by which an infected person or health department employee notifies others that they may have been exposed to the infected person in a manner known to transmit the infectious agent in question.

"Coronavirus infection, severe" means suspected or confirmed infection with severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV), Middle East respiratory syndrome (MERS)-associated coronavirus (MERS-CoV), or another coronavirus causing a severe acute illness.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy hazardous substances or organisms from a person, surface, or item to the point that such substances or organisms are no longer capable of causing adverse health effects and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the State Department of Health, also referred to as the Virginia Department of Health (VDH).

"Designee" or "designated officer or agent" means any person, or group of persons, designated by the State Health Commissioner, to act on behalf of the commissioner or the board.

"Ehrlichiosis/Anaplasmosis" means human infections caused by *Ehrlichia chaffeensis* (formerly included in the category "human monocytic ehrlichiosis" or "HME"), *Ehrlichia ewingii* or *Anaplasma phagocytophilum* (formerly included in the category "human granulocytic ehrlichiosis" or "HGE").

"Epidemic" means the occurrence in a community or region of cases of an illness clearly in excess of normal expectancy.

"Essential needs" means basic human needs for sustenance including but not limited to food, water, clothing, and health care (e.g., medications, therapies, testing, and durable medical equipment).

"Exceptional circumstances" means the presence, as determined by the commissioner in his sole discretion, of one or more factors that may affect the ability of the department to effectively control a communicable disease of public health threat. Factors to be considered include but are not limited to: (i) characteristics or suspected characteristics of the disease-causing organism or suspected disease-causing organism such as virulence, routes of transmission, minimum infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the existence and availability of demonstrated effective treatment; (ii) known or suspected risk factors for infection; (iii) the potential magnitude of the effect of the disease on the health and welfare of the public; and (iv) the extent of voluntary compliance with public health recommendations. The determination of exceptional circumstances by the commissioner may take into account the experience or results of investigation in Virginia, another state, or another country.

"Foodborne outbreak" means two or more cases of a similar illness acquired through the consumption of food contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to heavy metal intoxication, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, *Clostridium perfringens* food poisoning, hepatitis A, and Shiga toxin-producing *Escherichia coli* infection.

"Healthcare-associated infection" (also known as nosocomial infection) means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent or agents or its toxin or toxins that (i) occurs in a patient in a health care setting (e.g., a hospital or outpatient clinic), (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting, and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC.

"Hepatitis C, acute" means the following clinical characteristics are met: (i) discrete onset of symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum aminotransferase levels and the following laboratory criteria are met: (a) serum alanine aminotransferase levels (ALT) greater than 200 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done); and (d) hepatitis C virus antibody (anti-HCV) positive, HCV antigen positive, or HCV RNA positive by nucleic acid test.

"Hepatitis C, chronic" means that the laboratory criteria specified in clauses (b), (c) and (d) listed above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are not present and serum

alanine aminotransferase (ALT) levels do not exceed 200 IU/L. This category will include cases that may be acutely infected but not symptomatic.

"Immunization" means a procedure that increases the protective response of an individual's immune system to specified pathogens.

"Independent pathology laboratory" means a nonhospital or a hospital laboratory performing surgical pathology, including fine needle aspiration biopsy and bone marrow specimen examination services, which reports the results of such tests directly to physician offices, without reporting to a hospital or accessioning the information into a hospital tumor registry.

"Individual" means a person or companion animal. When the context requires it, "person or persons" shall be deemed to include any individual.

"Infection" means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent).

"Influenza A, novel virus" means infection of a human with an influenza A virus subtype that is different from currently circulating human influenza H1 and H3 viruses. Novel subtypes include H2, H5, H7, and H9 subtypes or influenza H1 and H3 subtypes originating from a nonhuman species.

"Invasive" means the organism is affecting a normally sterile site, including but not limited to blood or cerebrospinal fluid.

"Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of transmission, causation of, and other information pertinent to a disease occurrence.

"Isolation" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are infected with, or are reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, complete" means the full-time confinement or restriction of movement of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease. Modified isolation is designed to meet particular situations and includes but is not limited to the exclusion of children from school, the prohibition or restriction from engaging in a particular occupation or using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Isolation, protective" means the physical separation of a susceptible individual or individuals not infected with, or not reasonably suspected to be infected with, a communicable disease from an environment where transmission is occurring, or is reasonably suspected to be occurring, in order to prevent the individual or individuals from acquiring the communicable disease.

"Laboratory" as used herein means a clinical laboratory that examines materials derived from the human body for the purpose of providing information on the diagnosis, prevention, or treatment of disease.

"Laboratory director" means any person in charge of supervising a laboratory conducting business in the Commonwealth of Virginia.

"Law-enforcement agency" means any sheriff's office, police department, adult or youth correctional officer, or other agency or department that employs persons who have law-enforcement authority that is under the direction and control of the Commonwealth or any local governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia National Guard.

"Lead, reportable levels" means any detectable blood lead level in children 15 years of age and younger and levels greater than or equal to 5 μg/dL in a person older than 15 years of age.

"Least restrictive" means the minimal limitation of the freedom of movement and communication of an individual while under an order of isolation or an order of quarantine that also effectively protects unexposed and susceptible individuals from disease transmission.

"Medical care facility" means any hospital or nursing home licensed in the Commonwealth, or any hospital operated by or contracted to operate by an entity of the United States government or the Commonwealth of Virginia.

"Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of Nursing and Medicine or who is licensed by the Board of Medicine as a certified professional midwife.

"National Healthcare Safety Network or "NHSN" means a surveillance system created by the CDC for accumulating, exchanging, and integrating relevant information on infectious adverse events associated with health care delivery.

"Nucleic acid detection" means laboratory testing of a clinical specimen to determine the presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious agent using any method, including hybridization, sequencing, or amplification such as polymerase chain reaction.

"Nurse" means any person licensed as a professional nurse or as a licensed practical nurse by the Virginia Board of Nursing.

"Occupational outbreak" means a cluster of illness or disease that is indicative of a work-related exposure. Such conditions include but are not limited to silicosis, asbestosis, byssinosis, pneumoconiosis, and tuberculosis.

"Outbreak" means the occurrence of more cases of a disease than expected.

"Period of communicability" means the time or times during which the etiologic agent may be transferred directly or indirectly from an infected person to another person, or from an infected animal to a person.

"Physician" means any person licensed to practice medicine or osteopathy by the Virginia Board of Medicine.

"Quarantine" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are present within an affected area or who are known to have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease and who do not yet show signs or symptoms of infection with the communicable disease in order to prevent or limit the transmission of the communicable disease of public health threat to unexposed and uninfected individuals.

"Quarantine, complete" means the full-time confinement or restriction of movement of an individual or individuals who do not have signs or symptoms of infection but may have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease of public health threat in order to prevent the transmission of the communicable disease of public health threat to uninfected individuals.

"Quarantine, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals who do not have signs or symptoms of the infection but have been exposed to, or are reasonably suspected to have been exposed to, a communicable disease of public health threat. Modified quarantine may be designed to meet particular situations and includes but is not limited to limiting movement to the home, work, or one or more other locations, the prohibition or restriction from using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Reportable disease" means an illness due to a specific toxic substance, occupational exposure, or infectious agent, which affects a susceptible individual, either directly, as from an infected animal or person, or indirectly through an intermediate host, vector, or the environment, as determined by the board.

"School" means (i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth, (ii) any private or religious school that offers instruction at any level or grade from kindergarten through grade 12; and (iii) any private or religious nursery school or preschool, or any private or religious child care center required to be licensed by the Commonwealth.

"Serology" means the testing of blood, serum, or other body fluids for the presence of antibodies or other markers of an infection or disease process.

"Surveillance" means the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice. A surveillance system includes the functional capacity for data analysis as well as the

timely dissemination of these data to persons who can undertake effective prevention and control activities.

"Susceptible individual" means a person or animal who is vulnerable to or potentially able to contract a disease or condition. Factors that affect an individual's susceptibility include but are not limited to physical characteristics, genetics, previous or chronic exposures, chronic conditions or infections, immunization history, or use of medications.

"Toxic substance" means any substance, including any raw materials, intermediate products, catalysts, final products, or by-products of any manufacturing operation conducted in a commercial establishment, that has the capacity, through its physical, chemical or biological properties, to pose a substantial risk of death or impairment either immediately or over time, to the normal functions of humans, aquatic organisms, or any other animal but not including any pharmaceutical preparation which deliberately or inadvertently is consumed in such a way as to result in a drug overdose.

"Tubercle bacilli" means disease-causing organisms belonging to the *Mycobacterium tuberculosis* complex and includes *Mycobacterium tuberculosis*, *Mycobacterium bovis*, and *Mycobacterium africanum* or other members as may be established by the commissioner.

"Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli, performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is observed 48-72 hours after placement and palpable induration is measured across the diameter transverse to the long axis of the arm. The measurement of the indurated area is recorded in millimeters and the significance of the measured induration is based on existing national and department guidelines.

"Tuberculosis" means a disease caused by tubercle bacilli.

"Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"), as defined by § 32.1-49.1 of the *Code of Virginia*, means a disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear, and where sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in Virginia; or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing, or suspected of containing, tubercle bacilli is unobtainable.

"Tuberculosis infection in children age <4 years" means a significant reaction resulting from a tuberculin skin test (TST) or other approved test for latent infection without clinical or radiographic evidence of active tuberculosis disease, in children from birth up to their fourth birthday.

"Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected events in persons who received the smallpox vaccine or their contacts, including but not limited to bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia, progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or encephalomyelitis, ocular vaccinia, and fetal vaccinia.

"Waterborne outbreak" means two or more cases of a similar illness acquired through the ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to giardiasis, viral gastroenteritis, cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an outbreak.

PART II.

GENERAL INFORMATION

12 VAC 5-90-20. Authority.

Chapter 2 of Title 32.1 of the *Code of Virginia* deals with the reporting and control of diseases. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, § 32.1-42 of the *Code of Virginia* authorizes the board to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to the public health. Section 32.1-12 of the *Code of Virginia* empowers the Board of Health to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the Commissioner of the Department of Health.

12 VAC 5-90-30. Purpose.

This chapter is designed to provide for the uniform reporting of diseases of public health importance occurring within the Commonwealth in order that appropriate control measures may be instituted to reduce the occurrence of disease.

12 VAC 5-90-40. Administration.

A. The State Board of Health ("board") has the responsibility for promulgating regulations pertaining to the reporting and control of diseases of public health importance and to meet any emergency or to prevent a potential emergency caused by a disease dangerous to the public health including but not limited to specific procedures for responding to any disease listed pursuant to § 32.1-35 of the *Code of Virginia* that is determined to be caused by an agent or substance used as a weapon or any communicable disease of public health threat that is involved in an order of quarantine or an order of isolation pursuant to Article 3.02 (§ 32.1-48.05 et seq.) of the *Code of Virginia*.

B. The State Health Commissioner ("commissioner") is the executive officer for the State Board of Health with the authority of the board when it is not in session, subject to the rules and regulations of and review by the board. The commissioner has the authority to require quarantine, isolation, immunization, decontamination, or treatment of any individual or group of individuals when he determines any such measure to be necessary to control the spread of any disease of public health importance and has the authority to issue

orders of isolation pursuant to Article 3.01 (§ 32.1-48.01 et seq.) of the *Code of Virginia* and orders of quarantine and orders of isolation under exceptional circumstances involving any communicable disease of public health threat pursuant to Article 3.02 (§ 32.1-48.05 et seq.) of the *Code of Virginia*.

C. The local health director is responsible for the surveillance and investigation of those diseases specified by this chapter which occur in his jurisdiction. He is further responsible for reporting all such surveillance and investigations to the Office of Epidemiology. In cooperation with the commissioner, he is responsible for instituting measures for disease control, which may include implementing the quarantine and isolation orders of the commissioner.

D. The Office of Epidemiology, an organizational part of the department, is responsible for the statewide surveillance of those diseases specified by this chapter, for defining and disseminating appropriate disease control protocols for an outbreak situation, for coordinating the investigation of those diseases with the local health director, and for providing direct assistance where necessary. The Director of the Office of Epidemiology acts as the commissioner's designee in reviewing reports and investigations of diseases and recommendations by local health directors for quarantine or isolation. However, authority to order quarantine or isolation resides solely with the commissioner.

E. All persons responsible for the administration of this chapter shall ensure that the anonymity of patients and practitioners is preserved, according to state and federal law including the provisions of §§ 32.1-38, 32.1-41, and 32.1-71 of the *Code of Virginia*.

12 VAC 5-90-70. Powers and Procedures of Chapter Not Exclusive.

The board reserves the right to authorize a procedure for enforcement of this chapter which is not inconsistent with the provisions set forth herein and the provisions of Chapter 2 (§ 32.1-35 et seq.) of Title 32.1 of the *Code of Virginia*.

PART III.

REPORTING OF DISEASE

12 VAC 5-90-80. Lists of diseases that shall be reported.

A. Reportable disease list.

The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Acquired immunodeficiency syndrome (AIDS)

Amebiasis

*Anthrax

Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)

Babesiosis

*Botulism

*Brucellosis

Campylobacteriosis

Chancroid

Chickenpox (Varicella)

Chlamydia trachomatis infection

*Cholera

*Coronavirus infection, severe

Creutzfeldt-Jakob disease if <55 years of age

Cryptosporidiosis

Cyclosporiasis

*Diphtheria

*Disease caused by an agent that may have been used as a weapon

Ehrlichiosis/Anaplasmosis

Escherichia coli infection, Shiga toxin-producing

Giardiasis

Gonorrhea

Granuloma inguinale

**Haemophilus influenzae* infection, invasive

Hantavirus pulmonary syndrome

Hemolytic uremic syndrome (HUS)

*Hepatitis A

Hepatitis B (acute and chronic)

Hepatitis C (acute and chronic)

Hepatitis, other acute viral

Human immunodeficiency virus (HIV) infection

Influenza

*Influenza-associated deaths in children <18 years of age

Lead, reportable levels

Legionellosis

Leprosy (Hansen's disease)

Leptospirosis

Listeriosis

Lyme disease

Lymphogranuloma venereum

Malaria

*Measles (Rubeola)

*Meningococcal disease

Mumps

Ophthalmia neonatorum

*Outbreaks, all (including but not limited to foodborne, healthcare-associated, occupational, toxic substance-related, and waterborne)

*Pertussis

*Plague

*Poliovirus infection, including poliomyelitis

*Psittacosis

*Q fever

*Rabies, human and animal

Rabies treatment, post-exposure

*Rubella, including congenital rubella syndrome

Salmonellosis

Shigellosis

*Smallpox (Variola)

Spotted fever rickettsiosis

Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant

Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive, in children <5 years of age

Syphilis (report *primary and *secondary syphilis by rapid means)

Tetanus

Toxic substance-related illness

Trichinosis (Trichinellosis)

*Tuberculosis, active disease

Tuberculosis infection in children <4 years of age

*Tularemia

*Typhoid/Paratyphoid fever

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

*Vibrio infection

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis

B. Conditions reportable by directors of laboratories.

Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Amebiasis - by microscopic examination, culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Anthrax - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Arboviral infection - e.g., CHIK, dengue, EEE, LAC (also known as California encephalitis), SLE, WNV, Zika - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Babesiosis - by culture, antigen detection, nucleic acid detection, microscopic examination, or serologic results consistent with recent infection

*Botulism - by culture, nucleic acid detection, or identification of neurotoxin in a clinical specimen

*Brucellosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Campylobacteriosis - by culture or culture-independent diagnostic test (CIDT) (i.e., antigen detection or nucleic acid detection). For CIDT, also submit all available culture results (positive or negative) associated with a positive result.

Chancroid - by culture, antigen detection, or nucleic acid detection

Chickenpox (Varicella) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Chlamydia trachomatis infection - by culture, antigen detection, nucleic acid detection or, for lymphogranuloma venereum, serologic results consistent with recent infection

*Cholera - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Coronavirus infection, severe - by culture, nucleic acid detection, or serologic results consistent with recent infection

Creutzfeldt-Jakob disease if <55 years of age - by histopathology in patients under the age of 55 years

Cryptosporidiosis - by microscopic examination, antigen detection, or nucleic acid detection

Cyclosporiasis - by microscopic examination or nucleic acid detection

*Diphtheria - by culture or histopathology

Ehrlichiosis/Anaplasmosis - by culture, nucleic acid detection, microscopic examination, or serologic results consistent with recent infection

Escherichia coli infection, Shiga toxin-producing - by culture, Shiga toxin detection (e.g., nucleic acid detection, EIA), or serologic results consistent with recent infection

Giardiasis - by microscopic examination, antigen detection, or nucleic acid detection

Gonorrhea - by microscopic examination of a urethral smear (males only) or endocervical smear (females only), culture, antigen detection, or nucleic acid detection. Include available antimicrobial susceptibility findings in report.

**Haemophilus influenzae* infection, invasive - by culture, antigen detection, or nucleic acid detection from a normally sterile site

Hantavirus pulmonary syndrome - by antigen detection (immuno-histochemistry), nucleic acid detection, or serologic results consistent with recent infection

*Hepatitis A - by detection of IgM antibodies

Hepatitis B (acute and chronic) - by detection of HBsAg, HBeAg, or IgM antibodies or nucleic acid detection. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Hepatitis C (acute and chronic) - by hepatitis C virus antibody (anti-HCV) positive, HCV antigen positive, or HCV RNA positive by nucleic acid test. For all hepatitis C patients, also report available results of serum alanine

aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis, other acute viral – any finding indicative of acute infection with hepatitis D, E, or other cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Human immunodeficiency virus (HIV) infection - by culture, antigen detection, nucleic acid detection, or detection of antibody. For HIV-infected patients, report all results of CD4 and HIV viral load tests, including undetectable viral loads. For HIV-infected patients, report all HIV genetic nucleotide sequence data associated with HIV drug resistance tests by electronic submission. For children less than three years of age, report all tests regardless of the test findings (e.g., negative or positive).

Influenza - by culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection

Lead, reportable levels - by any detectable blood lead level in children ages 0-15 years or levels greater than or equal to 5 µg/dL in persons older than 15 years of age.

Legionellosis - by culture, antigen detection (including urinary antigen), nucleic acid detection, or serologic results consistent with recent infection

Leptospirosis - by culture, microscopic examination by dark field microscopy, nucleic acid detection, or serologic results consistent with recent infection

Listeriosis - by culture from a normally sterile site. If associated with miscarriage or stillbirth, by culture from placental or fetal tissue

Lyme disease - by culture, antigen detection, or detection of antibody confirmed with a supplemental test

Malaria - by microscopic examination, antigen detection, or nucleic acid detection

*Measles (Rubeola) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Meningococcal disease - by culture, nucleic acid detection, or antigen detection from a normally sterile site

Mumps - by culture, nucleic acid detection, or serologic results consistent with recent infection

*Mycobacterial diseases - (See 12VAC5-90-225 B) Report any of the following:

1. Acid fast bacilli by microscopic examination;

2. Mycobacterial identification - preliminary and final identification by culture or nucleic acid detection;

3. Drug susceptibility test results for *M. tuberculosis*.

*Pertussis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Plague - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Poliovirus infection - by culture

*Psittacosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Q fever - by culture, antigen detection, nucleic acid detection, immunohistochemical methods, or serologic results consistent with recent infection

*Rabies, human and animal - by culture, antigen detection by direct fluorescent antibody test, nucleic acid detection, or, for humans only, serologic results consistent with recent infection

*Rubella - by culture, nucleic acid detection, or serologic results consistent with recent infection

Salmonellosis - by culture, antigen detection, or nucleic acid detection

Shigellosis - by culture, antigen detection, or nucleic acid detection

*Smallpox (Variola) - by culture or nucleic acid detection

Spotted fever rickettsiosis - by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

Staphylococcus aureus infection, resistant, as defined below:

Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection - by antimicrobial susceptibility testing of a *Staphylococcus aureus* isolate, with a vancomycin susceptibility result of intermediate or resistant, cultured from a clinical specimen. Include available anti-microbial susceptibility findings in report.

Streptococcal disease, Group A, invasive or toxic shock - for invasive disease, by culture from a normally sterile site; for streptococcal toxic shock, by culture from any body site

Streptococcus pneumoniae infection, invasive, in children <5 years of age - by culture from a normally sterile site in a child under the age of five years

*Syphilis - by darkfield microscopy, antigen detection, nucleic acid detection, or serology by either treponemal or nontreponemal methods

Toxic substance-related illness - by blood or urine laboratory findings above the normal range, including but not limited to heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).

Trichinosis (Trichinellosis) - by microscopic examination of a muscle biopsy or serologic results consistent with recent infection

*Tularemia - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Typhoid/Paratyphoid fever - by culture, antigen detection, or nucleic acid detection

*Vaccinia, disease or adverse event - by culture or nucleic acid detection

*Vibrio infection - isolation of any species of the family Vibrionaceae (other than toxigenic *Vibrio cholera* O1 or O139, which are reportable as cholera) from a clinical specimen by culture, antigen detection, or nucleic acid detection

*Viral hemorrhagic fever - by culture, antigen detection (including immuno-histochemical staining), nucleic acid detection, or serologic results consistent with recent infection

*Yellow fever - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Yersiniosis - by culture, nucleic acid detection, or serologic results consistent with recent infection

C. Reportable diseases requiring rapid communication.

Certain of the diseases in the list of reportable diseases, because of their extremely contagious nature or their potential for greater harm, or both, require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed below, shall be made immediately by the most rapid means available, preferably by telephone to the local health department. (These same diseases are also identified by an asterisk (*) in subsections A and B, where applicable, of this section.)

Anthrax

Botulism

Brucellosis

Cholera

Coronavirus infection, severe

Diphtheria

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza-associated deaths in children <18 years of age

Influenza A, novel virus

Measles (Rubeola)

Meningococcal disease

Outbreaks, all

Pertussis

Plague

Poliovirus infection, including poliomyelitis

Psittacosis

Q fever

Rabies, human and animal

Rubella, including congenital rubella syndrome

Smallpox (Variola)

Syphilis, primary and secondary

Tuberculosis, active disease

Tularemia

Typhoid/Paratyphoid fever

Unusual occurrence of disease of public health concern

Vaccinia, disease or adverse event

Vibrio infection

Viral hemorrhagic fever
Yellow fever

D. Toxic substance-related illnesses.

Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or radioactive substance, shall be reported.

If such illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be made immediately by the most rapid means available, preferably by telephone.

E. Outbreaks.

The occurrence of outbreaks or clusters of any illness which may represent a group expression of an illness which may be of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone.

F. Unusual or ill-defined diseases or emerging or reemerging pathogens.

Unusual or emerging conditions of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone. In addition, the commissioner or his designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases. Such surveillance may be established to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public health. Any person reporting information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia.*

12 VAC 5-90-90. Those Required to Report.

A. Physicians.

Each physician who treats or examines any person who is suffering from or who is suspected of having a reportable disease or condition shall report that person's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease diagnosed or suspected; the date of onset of illness; available laboratory tests and results; and the name, address, and telephone number of the physician and medical facility where the examination was made, except that influenza should be reported by number of cases only (and type of influenza, if available). Reports are to be made to the local health department serving the jurisdiction where the physician practices. A physician may designate someone to report on his behalf, but the physician remains responsible for ensuring that the appropriate report is made. Any physician, designee, or organization making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia.*

Such reports shall be made on a Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a CDC or VDH surveillance form that provides the same information and shall be made within three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the

jurisdiction in which the facility is located. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.

Additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X (12VAC5-90-225 et seq.) for details on these requirements.

B. Directors of laboratories.

Laboratory directors shall report any laboratory examination of any clinical specimen, whether performed in-house or referred to an out-of-state laboratory, which yields evidence, by the laboratory method(s) indicated or any other confirmatory test, of a disease listed in 12VAC5-90-80 B.

Each report shall give the source of the specimen and the laboratory method and result; the name, address, age, date of birth, race, sex, and pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician at whose request and medical facility at which the examination was made. When the influenza virus is isolated, the type should be reported, if available. Reports shall be made within three days of identification of evidence of disease, except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1 or on the laboratory's own form if it includes the required information. Computer generated reports containing the required information may be submitted. Reporting may be done by means of secure electronic transmission upon agreement of the laboratory director and the department. Reports of HIV genetic nucleotide sequence data associated with HIV drug resistance tests must be submitted electronically. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*.

A laboratory identifying evidence of any of the following conditions shall notify the local health department of the positive culture or other positive test result within the timeframes specified in 12VAC5-90-80 and submit the initial isolate or other initial specimen to the Division of Consolidated Laboratory Services within seven days of identification. All specimens must be identified with the patient and physician information required in this subsection.

Anthrax

Botulism

Brucellosis

Cholera

Diphtheria

E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing *E. coli* should forward all positive stool specimens or positive enrichment broths to the Division of Consolidated Laboratory Services for confirmation and further characterization.)

Haemophilus influenzae infection, invasive

Influenza A, novel virus

Listeriosis

Meningococcal disease

Pertussis

Plague

Poliovirus infection

Q fever

Salmonellosis

Shigellosis

Streptococcal disease, Group A, invasive

Tuberculosis (A laboratory identifying *Mycobacterium tuberculosis* complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to the Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.)

Tularemia

Typhoid/Paratyphoid fever

Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection

Vibrio infection, including infections due to *Photobacterium damselae* and *Grimontia hollisae*

Yersiniosis

Other diseases as may be requested by the health department

When a clinical specimen yields evidence indicating the presence of a select agent or toxin as defined by federal regulations in 42 CFR Part 73, the person in charge of the laboratory shall contact the Division of Consolidated Laboratory Services and arrange to forward an isolate for confirmation. If a select agent or toxin has been confirmed in a clinical specimen, the laboratory director shall consult with Division of Consolidated Laboratory Services or CDC regarding isolate transport or destruction.

Laboratories operating within a medical care facility shall be considered to be in compliance with the requirement to notify the local health department when the director of that medical care facility assumes the reporting responsibility; however, laboratories are still required to submit isolates to the Division of Consolidated Laboratory Services or other designated laboratory as noted in this subsection.

C. Persons in charge of a medical care facility.

Any person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a physician. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*. The requirement to report shall include all inpatient, outpatient, and emergency care departments within the medical care facility. Such report shall contain the patient's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease being reported; available laboratory tests and results; the date of admission; hospital chart number; date expired (when applicable); and attending physician. Influenza should be reported by number of cases only (and type of influenza, if available). Reports shall be made within three days of the suspicion or confirmation of disease except that those identified in 12VAC5-90-80 C shall be reported immediately by the most rapid means available, preferably by telephone, to the local health department serving the jurisdiction in which the facility is located. Reports shall be made on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a CDC or VDH surveillance form that

provides the same information. Reporting may be done by means of secure electronic transmission upon agreement of the medical care facility and the department.

A person in charge of a medical care facility may assume the reporting responsibility on behalf of the director of the laboratory operating within the facility.

D. Persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp.

Any person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, or a school, child care center, or summer camp as defined in § 35.1-1 of the *Code of Virginia* shall report immediately to the local health department the presence or suspected presence in his program, service, facility, school, child care center, or summer camp of persons who have common symptoms suggesting an outbreak situation. Such persons may report additional information, including identifying and contact information for individuals with communicable diseases of public health concern or individuals who are involved in outbreaks that occur in their facilities, as necessary to facilitate public health investigation and disease control. Any person so reporting shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia.*

E. Local health directors.

The local health director shall forward any report of a disease or report of evidence of a disease which has been made on a resident of his jurisdiction to the Office of Epidemiology within three days of receipt. This report shall be submitted immediately by the most rapid means available if the disease is one requiring rapid communication, as required in 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office of Epidemiology, by either a paper report or entry into a shared secure electronic disease surveillance system, within three days. Furthermore, the local health director shall immediately forward to the appropriate local health director any disease reports on individuals residing in the latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia. The Office of Epidemiology shall be responsible for notifying other state health departments of reported illnesses in their residents and for notifying CDC as necessary and appropriate.

F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities.

In accordance with § 32.1-37.1 of the *Code of Virginia*, any person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

Creutzfeldt-Jakob disease

Human immunodeficiency virus infection

Hepatitis B

Hepatitis C

Rabies
Smallpox
Syphilis, infectious
Tuberculosis, active disease
Vaccinia, disease or adverse event
Viral hemorrhagic fever

G. Employees, conditional employees, and persons in charge of food establishments.

12VAC5-421-80 of the Food Regulations requires a food employee or conditional employee to notify the person in charge of the food establishment when diagnosed with certain diseases that are transmissible through food and requires the person in charge of the food establishment to notify the regulatory authority. Refer to 12VAC5-421-80 for further guidance and clarification regarding these reporting requirements.

PART IV.

CONTROL OF DISEASE

12 VAC 5-90-100. Methods.

The board and commissioner shall use appropriate disease control measures to manage the diseases listed in 12VAC5-90-80 A, including but not limited to those described in the "Methods of Control" sections of the 20th Edition of the Control of Communicable Diseases Manual (2015) published by the American Public Health Association. The board and commissioner reserve the right to use any legal means to control any disease which is a threat to the public health.

When notified about a disease specified in 12VAC5-90-80, the local health director or his designee shall have the authority and responsibility to perform contact tracing/contact services for HIV infection, infectious syphilis, and active tuberculosis disease and may perform contact services for the other diseases if deemed necessary to protect the public health. All contacts of HIV infection shall be afforded the opportunity for appropriate counseling, testing, and individual face-to-face disclosure of their test results. In no case shall names of informants or infected individuals be revealed to contacts by the health department. All information obtained shall be kept strictly confidential.

The local health director or his designee shall review reports of diseases received from his jurisdiction and follow up such reports, when indicated, with an appropriate investigation in order to evaluate the severity of the problem. The local health director or his designee may recommend to any individual or group of individuals appropriate public health control measures, including but not limited to quarantine, isolation, immunization, decontamination, or treatment. He shall determine in consultation with the Office of Epidemiology and the commissioner if further investigation is required and if one or more forms of quarantine, isolation, or both will be necessary.

Complete isolation shall apply to situations where an individual is infected with a communicable disease of public health significance (including but not limited to active tuberculosis disease or HIV infection) and is engaging in behavior that places others at risk for infection with the communicable disease of public health significance, in accordance with the provisions of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia*.

Modified isolation shall apply to situations in which the local health director determines that modifications of activity are necessary to prevent disease transmission. Such situations shall include but are not limited to the temporary exclusion of a child with a communicable disease from school, the temporary exclusion of an individual with a communicable disease from food handling or patient care, the temporary prohibition or restriction of an individual with a communicable disease from using public transportation, the requirement that a person with a communicable disease use certain personal protective equipment, or restrictions of other activities that may pose a risk to the health of others.

Protective isolation shall apply to situations such as the exclusion, under § 32.1-47 of the *Code of Virginia*, of any unimmunized child from a school in which an outbreak, potential epidemic, or epidemic of a vaccine preventable disease has been identified.

To the extent permitted by the *Code of Virginia*, the local health director may be authorized as the commissioner's designee to implement the forms of isolation described in this section. When these forms of isolation are deemed to be insufficient, the local health director may use the provisions of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* for the control of communicable diseases of public health significance or, in consultation with the Office of Epidemiology, shall provide sufficient information to enable the commissioner to prepare an order or orders of isolation, quarantine, or both under Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* for the control of communicable diseases of public health threat.

12 VAC 5-90-103. Isolation for Communicable Disease of Public Health Threat.

A. Application.

The commissioner, in his sole discretion, may invoke the provisions of Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* and may declare the isolation of any individual or individuals upon a determination that:

1. Such individual or individuals are known to have been infected with or are reasonably suspected to have been infected with a communicable disease of public health threat;

2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* to be insufficient, or the individual or individuals have failed or refused to comply voluntarily with the control measures directed by the commissioner in response to a communicable disease of public health threat; and

3. Isolation is the necessary means to contain a communicable disease of public health threat, to ensure that such isolated individual or individuals receive appropriate medical treatment subject to the provisions of § 32.1-44 of the *Code of Virginia*, or to protect health care providers and others who may come into contact with such infected individual or individuals.

The commissioner, in his sole discretion, may also order the isolation of an affected area if, in addition to the above, the Governor has declared a state of emergency

for such affected area of the Commonwealth.

B. Documentation.

For isolation for a communicable disease of public health threat, information about the infection or suspected infection; the individual, individuals, and/or affected area; and the nature or suspected nature of the exposure shall be duly recorded by the local health department in consultation with the Office of Epidemiology. This information shall be sufficient to enable documenting a record of findings and to enable the commissioner to prepare the order of isolation, including the information required in § 32.1-48.12 of the *Code of Virginia*. In addition, sufficient information on individuals shall be maintained by the local health department to enable appropriate follow-up of individuals for health status evaluation and treatment as well as compliance with the order of isolation.

The commissioner shall ensure that the protected health information of any individual or individuals subject to the order of isolation is disclosed only in compliance with state and federal law.

C. Means of isolation.

The local health department shall assess the situation, and in consultation with the Office of Epidemiology, identify the least restrictive means of isolation that effectively protects unexposed and susceptible individuals. The place of isolation selected shall allow the most freedom of movement and communication with family members and other contacts without allowing disease transmission to other individuals and shall allow the appropriate level of medical care needed by isolated individuals to the extent practicable. The commissioner, in his sole discretion, may order the isolated individual or individuals to remain in their residences, to remain in another place where they are present, or to report to a place or places designated by the commissioner for the duration of their isolation.

The commissioner's order of isolation shall be for a duration consistent with the known period of communicability of the communicable disease of public health threat or, if the course of the disease is unknown or uncertain, for a period anticipated as being consistent with the period of communicability of other similar infectious agents. In the situation where an area is under isolation, the duration of isolation shall take into account the transmission characteristics and known or suspected period of communicability.

D. Delivery.

The local health department shall deliver the order of isolation, or ensure its delivery by an appropriate party such as a law-enforcement officer or health department employee, to the affected individual or individuals in person to the extent practicable. If, in the opinion of the commissioner, the scope of the notification would exceed the capacity of the local health department to ensure individual notification in a timely manner, then print, radio, television, internet, and/or other available means shall be used to inform those affected.

E. Enforcement.

Upon finding that there is probable cause to believe that any individual or individuals who are subject to an order of isolation may fail or refuse to comply with such order, the commissioner in his sole discretion may include in the order a requirement that such individual or individuals are to be taken immediately into custody by law-

enforcement agencies and detained for the duration of the order of isolation or until the commissioner determines that the risk of noncompliance is no longer present. For any individual or individuals identified as, or for whom probable cause exists that he may be, in violation of any order of isolation, or for whom probable cause exists that he may fail or refuse to comply with any such order, the enforcement authority directed by the commissioner to law-enforcement agencies shall include but need not be limited to the power to detain or arrest.

Any individual or individuals so detained shall be held in the least restrictive environment that can provide any required health care or other services for such individual. The commissioner shall ensure that law-enforcement personnel responsible for enforcing an order or orders of isolation are informed of appropriate measures to take to protect themselves from contracting the disease of public health threat.

F. Health status monitoring.

The local health department shall monitor the health of those under isolation either by regular telephone calls, visits, self-reports, or by reports of caregivers or healthcare providers or by other means.

G. Essential needs.

Upon issuance of an order of isolation to an individual or individuals by the commissioner, the local health department shall manage the isolation, in conjunction with local emergency management resources, such that individual essential needs can be met to the extent practicable. Upon issuance of an order of isolation by the commissioner for an affected area, existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of the *Code of Virginia* shall be utilized for mobilizing appropriate resources to ensure essential needs are met.

H. Appeals.

Any individual or individuals subject to an order of isolation or a court-ordered confirmation or extension of any such order may file an appeal of the order of isolation in accordance with the provisions of § 32.1-48.13 of the *Code of Virginia*. An appeal shall not stay any order of isolation.

I. Release from isolation.

Once the commissioner determines that an individual or individuals no longer pose a threat to the public health, the order of isolation has expired, or the order of isolation has been vacated by the court, the individual or individuals under the order of isolation shall be released immediately. If the risk of an infected individual transmitting the communicable disease of public health threat to other individuals continues to exist, an order of isolation may be developed to extend the restriction prior to release from isolation.

J. Affected area.

If the criteria in subsection A of this section are met and an area is known or suspected to have been affected, then the commissioner shall notify the Governor of the situation and the need to order isolation for the affected area during the known or suspected time of exposure. In order for an affected area to be isolated, the Governor must declare a state of emergency for the affected area.

If an order of isolation is issued for an affected area during the known or suspected time of exposure, the commissioner shall cause the order of isolation to be communicated to the individuals residing or

located in the affected area. The use of multiple forms of communication, including but not limited to radio, television, internet, and/or other available means, may be required in order to reach the individuals who were in the affected area during the known or suspected time of exposure.

The provisions for documentation, means of isolation, enforcement, health status monitoring, essential needs, and release from isolation described above will apply to the isolation of affected areas. Appropriate management of a disease of public health threat for an affected area may require the coordinated use of local, regional, state, and national resources. In specifying one or more affected areas to be placed under isolation, the objective will be to protect as many people as possible using the least restrictive means. As a result, defining the precise boundaries and time frame of the exposure may not be possible, or may change as additional information becomes available. When this occurs, the commissioner shall ensure that the description of the affected area is in congruence with the Governor's declaration of emergency and shall ensure that the latest information is communicated to those in or exposed to the affected area.

12 VAC 5-90-107. Quarantine.

A. Application.

The commissioner, in his sole discretion, may invoke the provisions of Article 3.02 (§ 32.1-48.05 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* and may order a complete or modified quarantine of any individual or individuals upon a determination that:

1. Such individual or individuals are known to have been exposed to or are reasonably suspected to have been exposed to a communicable disease of public health threat;

2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) of Chapter 2 of Title 32.1 of the *Code of Virginia* to be insufficient, or the individual or individuals have failed or refused to comply voluntarily with the control measures directed by the commissioner in response to a communicable disease of public health threat; and

3. Quarantine is the necessary means to contain a communicable disease of public health threat to which an individual or individuals have been or may have been exposed and thus may become infected.

The commissioner, in his sole discretion, may also order the quarantine of an affected area if, in addition to the above, the Governor has declared a state of emergency for such affected area of the Commonwealth.

B. Documentation.

For quarantine for a communicable disease of public health threat, information about the infection or suspected infection; the individual, individuals, and/or affected area; and the nature or suspected nature of the exposure shall be duly recorded by the local health department, in consultation with the Office of Epidemiology. This information shall be sufficient to enable documenting a record of findings and enable the commissioner to prepare a written order of quarantine, including the information required in § 32.1-48.09 of the *Code of Virginia*. In addition, sufficient information on individuals shall be maintained by the local health department to enable

appropriate follow-up of individuals for health status evaluation and treatment as well as compliance with the order of quarantine.

The commissioner shall ensure that the protected health information of any individual or individuals subject to the order of quarantine is disclosed only in compliance with state and federal law.

C. Means of quarantine.

The local health department shall assess the situation, and in consultation with the Office of Epidemiology, shall recommend to the commissioner the least restrictive means of quarantine that effectively protects unexposed and susceptible individuals. The place of quarantine selected shall allow the most freedom of movement and communication with family members and other contacts without allowing disease transmission to others.

The commissioner, in his sole discretion, may order the quarantined individual or individuals to remain in their residences, to remain in another place where they are present, or to report to a place or places designated by the commissioner for the duration of their quarantine.

The commissioner's order of quarantine shall be for a duration consistent with the known incubation period of the communicable disease of public health threat or, if the incubation period is unknown or uncertain, for a period anticipated as being consistent with the incubation period for other similar infectious agents. In the situation where an area is under quarantine, the duration of quarantine shall take into account the transmission characteristics and known or suspected incubation period.

D. Delivery.

The local health department shall deliver the order of quarantine, or ensure its delivery by an appropriate party such as a law-enforcement officer or health department employee, to the affected individual or individuals in person to the extent practicable. If, in the opinion of the commissioner, the scope of the notification would exceed the capacity of the local health department to ensure notification in a timely manner, then print, radio, television, internet, and/or other available means shall be used to inform those affected.

E. Enforcement.

Upon finding that there is probable cause to believe that any individual or individuals who are subject to an order of quarantine may fail or refuse to comply with such order, the commissioner in his sole discretion may include in the order a requirement that such individual or individuals to be taken immediately into custody by law-enforcement agencies and detained for the duration of the order of quarantine or until the commissioner determines that the risk of and from noncompliance is no longer present. For any individual or individuals identified as, or for whom probable cause exists that he may be, in violation of any order of quarantine, or for whom probable cause exists that he may fail or refuse to comply with any such order, the enforcement authority directed by the commissioner to law-enforcement agencies shall include but need not be limited to the power to detain or arrest.

Any individual or individuals so detained shall be held in the least restrictive environment that can provide any required health care or other services for such individual. The commissioner shall ensure

that law-enforcement personnel responsible for enforcing an order or orders of quarantine are informed of appropriate measures to take to protect themselves from contracting the disease of public health threat.

F. Health status monitoring.

The local health department shall monitor the health of those under quarantine either by regular telephone calls, visits, self-reports, or by reports of caregivers or healthcare providers or by other means. If an individual or individuals develop symptoms compatible with the communicable disease of public health threat, then 12 VAC 5-90-103 would apply to the individual or individuals.

G. Essential needs.

Upon issuance of an order of quarantine to an individual or individuals by the commissioner, the local health department shall manage the quarantine, in conjunction with local emergency management resources, such that individual essential needs can be met to the extent practicable. Upon issuance of an order of quarantine by the commissioner for an affected area, existing emergency protocols pursuant to Chapter 3.2 (§ 44-146.13 et seq.) of Title 44 of the *Code of Virginia* shall be utilized for mobilizing appropriate resources to ensure essential needs are met.

H. Appeals.

Any individual or individuals subject to an order of quarantine or a court-ordered confirmation or extension of any such order may file an appeal of the order of quarantine in accordance with the provisions of § 32.1-48.10 of the *Code of Virginia*. An appeal shall not stay any order of quarantine.

I. Release from quarantine.

Once the commissioner determines that an individual or individuals are no longer at risk of becoming infected and pose no risk of transmitting the communicable disease of public health threat to other individuals, the order of quarantine has expired, or the order of quarantine has been vacated by the court, the individuals under the order of quarantine shall be released immediately. If the risk of an individual becoming infected and transmitting the communicable disease of public health threat to other individuals continues to exist, an order of quarantine may be developed to extend the restriction prior to release from quarantine.

J. Affected area.

If the criteria in subsection A of this section are met and an area is known or suspected to have been affected, then the commissioner shall notify the Governor of the situation and the need to order quarantine for the affected area. In order for an affected area to be quarantined, the Governor must declare a state of emergency for the affected area.

If an order of quarantine is issued for an affected area, the commissioner shall cause the order of quarantine to be communicated to the individuals residing or located in the affected area. The use of multiple forms of communication, including but not limited to radio, television, internet, and/or other available means, may be required in order to reach the individuals who were in the affected area during the known or suspected time of exposure.

The provisions for documentation, means of quarantine, enforcement, health status monitoring, essential needs, and release from quarantine described above will apply

to the quarantine of affected areas. Appropriate management of a disease of public health threat for an affected area may require the coordinated use of local, regional, state, and national resources. In specifying one or more affected areas to be placed under quarantine, the objective will be to protect as many people as possible using the least restrictive means. As a result, defining the precise boundaries and time frame of the exposure may not be possible, or may change as additional information becomes available. When this occurs, the commissioner shall ensure that the description of the affected area is in congruence with the Governor's declaration of emergency and shall ensure that the latest information is communicated to those in or exposed to the affected area.

PART V.

IMMUNIZATION OF PERSONS LESS THAN 18 YEARS OF AGE

12VAC5-90-110. Dosage and age requirements for immunizations; obtaining immunizations.

A. Every person in Virginia less than 18 years of age shall be immunized in accordance with the most recent Immunization Schedule developed and published by the CDC, Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). Requirements for school and day care attendance are addressed in 12VAC5-110.

B. The required immunizations may be obtained from a physician, registered nurse, or other licensed professional as authorized by the *Code of Virginia*.

PART VI.

VENEREAL DISEASE

12 VAC 5-90-130. Prenatal Testing.

Every physician, physician assistant, or nurse practitioner attending a pregnant patient during gestation shall examine and test such patient for syphilis, hepatitis B surface antigen (HBsAg), and any other sexually transmitted disease as clinically indicated within fifteen days after beginning such attendance. A second prenatal test for syphilis and HBsAg shall be conducted at the beginning of the third trimester (28 weeks) for patients who are at higher risk for these diseases. Persons at higher risk for syphilis include those who have had multiple sexual partners within the previous year, those with any prior history of a sexually transmitted disease, and those living in communities and populations in which the prevalence of syphilis is high. Persons at higher risk for hepatitis B virus infection include injecting drug users and those with personal contact with a hepatitis B patient, multiple sexual partners, and/or occupational exposure to blood. If the patient first seeks care during the third trimester, only one test shall be required. As a routine component of prenatal care, every licensed practitioner who renders prenatal care, including any holder of a multistate licensure privilege to practice nursing, regardless of the site of such practice, shall inform every pregnant patient that human immunodeficiency virus (HIV) screening is recommended for all pregnant patients and that she will receive an HIV test as part of the routine panel of prenatal tests unless she declines (opt-out screening). The practitioner shall offer the pregnant patient oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the

meaning of positive and negative test results. The confidentiality provisions of § 32.1-36.1 of the *Code of Virginia*, and the test result disclosure conditions and appropriate counseling requirements of § 32.1-37.2 of the *Code of Virginia* shall apply to any HIV testing conducted pursuant to this section. The Centers for Disease Control and Prevention (CDC) recommends a second HIV test for patients who receive health care in jurisdictions with elevated incidence of HIV or AIDS among women aged 15 through 45 years, which includes Virginia. Practitioners should offer a second HIV test during the third trimester to all pregnant patients. Practitioners shall counsel all pregnant patients with HIV-positive test results about the dangers to the fetus and the advisability of receiving treatment in accordance with the then current CDC recommendations for HIV-positive pregnant patients. Any pregnant patient shall have the right to refuse testing for HIV infection and any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record.

PART VII.

PREVENTION OF BLINDNESS FROM OPHTHALMIA NEONATORUM

12 VAC 5-90-140. Procedure for Preventing Ophthalmia Neonatorum.

The physician, nurse or midwife in charge of the infant's care after delivery of a baby shall ensure that one of the following is administered in each eye of that newborn baby as soon as possible after birth: (i) two drops of a 1.0% silver nitrate solution; (ii) a 1-cm ribbon of 1.0% tetracycline ophthalmic ointment; or (iii) a 1-cm ribbon of 0.5% erythromycin ophthalmic ointment. This treatment shall be recorded in the medical record of the infant.

PART VIII.

CANCER REPORTING

12 VAC 5-90-150. Authority.

Article 9 (§ 32.1-70 et seq.) of Title 32.1 of the *Code of Virginia* authorizes the establishment of a statewide cancer registry.

12 VAC 5-90-160. Reportable Cancers and Tumors.

Clinically or pathologically diagnosed cancers, as defined in 12 VAC 5-90-10, and benign brain and central nervous system tumors shall be reported to the Virginia Cancer Registry in the department. Carcinoma *in situ* of the cervix is not reportable.

12 VAC 5-90-170. Those Required to Report.

Any person in charge of a medical care facility, clinic, or independent pathology laboratory which diagnoses or treats cancer patients is required to report. Physicians are required to report cases of cancer in those instances when it has been determined that a medical care facility, clinic, or in-state pathology laboratory has not reported. Any person making such report shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*.

12 VAC 5-90-180. Report Contents and Procedures.

Each report shall include the patient's name, address (including county or independent city of residence), age, date of birth, sex, date of diagnosis, date of admission or first contact, primary site of cancer, histology (including type, behavior, and grade), basis of diagnosis, social security number, race, ethnicity, marital status, usual occupation, usual industry, sequence number, laterality, stage, treatment, recurrence information

(when applicable), name of reporting facility, vital status, cause of death (when applicable), date of last contact, history of tobacco and alcohol use, and history of service in Vietnam and exposure to dioxin-containing compounds, when applicable.

Reporting shall be by electronic means where possible. Output file formats shall conform to the most recent version of the North American Association of Central Cancer Registries' standard data file layout. Facilities without electronic reporting means and physicians shall submit the required information on the Virginia Cancer Registry Reporting Form. A copy of the pathology report(s) should accompany each completed reporting form, when available. Medical care facilities and clinics reporting via the reporting form should also submit a copy of the admission form and discharge summary.

Reports shall be made within six months of the diagnosis of cancer and submitted to the Virginia Cancer Registry on a monthly basis. Cancer programs conducting annual follow-up on patients shall submit follow-up data monthly in an electronic format approved by the Virginia Cancer Registry.

PART IX.

PROTOCOL FOR IDENTIFICATION OF CHILDREN WITH ELEVATED BLOOD LEAD LEVELS

12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and information to be provided.

A. Schedule for testing.

Every child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in subsection B of this section. Children 25 months through 72 months of age who present for medical care and meet any of criteria of subsection B of this section shall also be tested if they have either not previously been tested for blood lead level or were previously tested but experienced a change since testing that has resulted in an increased risk of lead exposure based on the criteria listed in subsection B of this section.

B. Criteria for testing.

1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);

2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1960;

3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the last six months) ongoing or planned renovations;

4. The child is living in or regularly visiting a house, apartment, dwelling, or other structure in which one or more persons have blood lead testing yielding evidence of lead exposure;

5. The child is living with an adult whose job, hobby, or other activity involves exposure to lead;

6. The child is living near an active lead smelter, battery recycling plant, or other industry likely to release lead;

7. The child's parent, guardian, or other person standing in loco parentis requests the child's blood be tested due to any suspected exposure; or

8. The child is a recent refugee or immigrant or is adopted from outside of the United States.

C. Exceptions.

A child who does not meet any of the schedule or criteria provided in subsection A or B of this section is considered to be at low risk, and testing is not required but may be conducted at the discretion of the health care provider. The testing requirement shall be waived if the parent, guardian, or other person standing in loco parentis of a child objects to the testing on the basis that the procedure conflicts with his religious tenets or practices.

D. Confirmation of blood lead levels.

Blood lead level testing shall be performed on venous or capillary blood. Tests of venous blood performed by a laboratory certified by the federal Centers for Medicare & Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified), are considered confirmatory. Tests of venous blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory testing shall be performed in accordance with the following schedule:

1. Within one to three months if the result of the capillary test is at or above the CDC's reference value and up to 9 micrograms of lead per deciliter of whole blood (µg/dL).

2. Within one week to one month if the result of the capillary test is 10-44 µg/dL. The higher this test result, the more urgent the need for a confirmatory test.

3. Within 48 hours if the result of the capillary test is 45-59 µg/dL.

4. Within 24 hours if the result of the capillary test is 60-69 µg/dL.

5. Immediately as an emergency laboratory test if the result of the capillary test is 70 µg/dL or higher.

E. Information to be provided.

As part of regular well-check visits for all children, the health care provider shall make available to parents, guardians, or other persons standing in loco parentis information on the dangers of lead poisoning, potential sources of lead and ways to prevent exposure, and a list of available lead-related resources. When blood lead level testing is performed, the health care provider shall share the child's blood lead level test result with the child's parent, guardian, or other person standing in loco parentis and report to the local health department in accordance with the requirements of 12VAC5-90-80.

PART X.
TUBERCULOSIS CONTROL

12 VAC 5-90-225. Additional Data to be Reported Related to Persons with Active Tuberculosis Disease (Confirmed or Suspected).

A. Physicians and directors of medical care facilities are required to submit all of the following:

1. An initial report to be completed when there are reasonable grounds to suspect that a person has active TB disease, but no later than when antituberculosis drug therapy is initiated. The reports must include

the following: the affected person's name; age; date of birth; gender; address; pertinent clinical, radiographic, microbiologic and pathologic reports, whether pending or final; such other information as may be needed to locate the patient for follow-up; and name, address, and telephone number of the treating physician.

2. A secondary report to be completed simultaneously or within one to two weeks following the initial report. The report must include: the date and results of tuberculin skin test (TST); the date and results of the initial and any follow-up chest radiographs; the dates and results of bacteriologic or pathologic testing, the antituberculosis drug regimen, including names of the drugs, dosages and frequencies of administration, and start date; the date and results of drug susceptibility testing; HIV status; contact screening information; and name, address, and telephone number of treating physician.
3. Subsequent reports are to be made when updated information is available. Subsequent reports are required when: clinical status changes; the treatment regimen changes; treatment ceases for any reason; or there are any updates to laboratory results, treatment adherence, name, address, and telephone number of current provider, patient location or contact information, or other additional clinical information.

4. Physicians and/or directors of medical care facilities responsible for the care of a patient with active tuberculosis disease are required to develop and maintain a written treatment plan. This plan must be in place no later than the time when antituberculosis drug therapy is initiated. Patient adherence to this treatment plan must be documented. The treatment plan and adherence record are subject to review by the local health director or his designee at any time during the course of treatment.
5. The treatment plan for the following categories of patients must be submitted to the local health director or his designee for approval no later than the time when antituberculosis drug therapy is started or modified:

    a. For individuals who are inpatients or incarcerated, the responsible provider or facility must submit the treatment plan for approval prior to discharge or transfer.

    b. Individuals, whether inpatient, incarcerated, or outpatients, who also have one of the following conditions:

        (1) HIV infection

        (2) Known or suspected active TB disease resistant to rifampin, rifabutin, rifapentine or other rifamycin with or without resistance to any other drug.

        (3) A history of prior treated or untreated active TB disease, or a history of relapsed active TB disease.

        (4) A demonstrated history of nonadherence to any medical treatment regimen.

B. Laboratories are required to submit the following:

1. Results of smears that are positive for acid fast bacilli.

2. Results of cultures positive for any member of the *Mycobacterium tuberculosis* complex (i.e., *M. tuberculosis*, *M. bovis*, *M. africanum*) or any other mycobacteria.

3. Results of rapid methodologies, including acid hybridization or nucleic acid amplification, which are indicative of *M. tuberculosis* complex or any other mycobacteria.

4. Results of tests for antimicrobial susceptibility performed on cultures positive for tubercle bacilli.

5. Laboratories, whether testing is done in-house or referred to an out-of-state laboratory, shall submit a representative and viable sample of the initial culture positive for any member of the *M. tuberculosis* complex to the Virginia Division of Consolidated Laboratory Services or other laboratory designated by the board to receive such specimen.

PART XI.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) TESTING OF GAMETE DONORS

12 VAC 5-90-230. Definitions.

The following words and terms, when used in this regulation, shall have the following meaning unless the context clearly indicates otherwise:

"**Artificial insemination**" means instrumental placement of semen into the vagina, cervical canal, or uterus of a recipient.

"**Donor**" means an individual who is unrelated by marriage to the recipient and who contributes sperm or ova used in the following procedures: treatment of infertility by artificial insemination; in vitro fertilization; gamete intrafallopian tube transfer; zygote intrafallopian tube transfer or any other gamete, zygote, or embryo transfer; or other intervening medical technology using sperm or ova.

"**Embryo**" means the product of a fertilized ovum prior to the eighth week of development inside a uterus.

"**Gamete**" means either sperm or ova.

"**Gamete intrafallopian tube transfer**" means placement of harvested ova and sperm into the fallopian tube or tubes of a recipient.

"**HIV**-1" means the retrovirus causing the human immunodeficiency virus infection, type 1.

"**HIV-2**" means the retrovirus causing the human immunodeficiency virus infection, type 2.

"**In vitro fertilization**" means placement of a zygote or embryo that has been fertilized outside the body into the uterus of a recipient.

"**Zygote**" means a fertilized ovum prior to cell cleavage.

"**Zygote intrafallopian tube transfer**" means placement of a zygote or zygotes into the fallopian tube or tubes of a recipient.

12 VAC 5-90-240. Excluding Donors with High Risk Factors.

A. Practitioners using gametes for the treatment of infertility by transfer of such gametes to a recipient shall interview all gamete donors at the time of donation in order to screen for high risk behavior indicating potential exposure to HIV-1 and HIV-2.

B. Any gamete donor reporting infection with HIV-1 or HIV-2 or any of the following risk factors shall be excluded from donating:

1. Men who have had sex with another man within the preceding five years.

2. Persons who have injected drugs for a non-medical reason in the preceding five years, including intravenous, intramuscular, and subcutaneous injections of recreational or illegal drugs.

3. Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.

4. Persons who have had sex in exchange for money or drugs in the preceding five years.

5. Persons who have had sex in the preceding 12 months with any person described in Sections 1 through 4 above or with any person suspected of being infected with HIV-1 or HIV-2.

6. Persons who have been exposed within the last 12 months to known or suspected HIV-1 or HIV-2 infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, non-intact skin, or mucous membrane.

7. Current inmates of correctional systems (including jails and prisons), and individuals who have been incarcerated in jail or prison for more than 72 consecutive hours during the previous 12 months.

8. Persons who have had or have been treated for syphilis or gonorrhea during the preceding 12 months.

9. Persons who within 12 months of donation have undergone acupuncture, ear and/or body piercing or tattooing in which sterile procedures were not used, or where it is unknown if sterile procedures were used.

10. Persons who choose to defer from donation whether or not they report any of the above potential exposures to HIV-1 or HIV-2.

12 VAC 5-90-250. Storage of Semen Pending Negative HIV Tests.

Semen specimens from donors shall be stored and withheld from use for at least 180 days following donation and used only if the donor tests negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.

12 VAC 5-90-260. Use of Ova After Negative HIV Tests.

Ova shall be used only if the donor tests negative for serum antibodies to HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at the initiation of the cycle during which the ova are harvested.

12 VAC 5-90-270. Notifying Recipients of Option to Delay Transfer.

Practitioners using ova, embryos, or zygotes for the treatment of infertility or other medical technology involving the transfer of ova, embryos, or zygotes to a recipient shall notify these recipients of the option for having donor ova fertilized and the resultant zygotes frozen and then transferred to the recipient only if the ova donor is negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least 180 days after donation.

PART XII.

REPORTING OF DANGEROUS MICROBES AND PATHOGENS

12VAC5-90-280. Reporting of dangerous microbes and pathogens.

A. Definitions.

The following words and terms when used in this part shall have the following meanings unless the context clearly indicates otherwise:

"Biologic agent" means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or other living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

"CDC" means the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

"Diagnosis" means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety.

"Proficiency testing" means a sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated.

"Responsible official" means any person in charge of directing or supervising a laboratory conducting business in the Commonwealth of Virginia. At colleges and universities, the responsible official shall be the president of the college or university or his designee. At private, state, or federal organizations, the responsible official shall be the laboratory director or a chief officer of the organization or his designee.

"Select agent or toxin" or "select agent and toxin" means all those biological agents or toxins as defined by federal regulations in 42 CFR Part 73, including Health and Human Services select agents and toxins and overlap select agents and toxins.

"Toxin" means the toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa); or infectious substances; or a recombinant or

synthesized molecule, whatever the origin and method of production; and includes any poisonous substance or biological product that may be engineered as a result of biotechnology or produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

"Verification" means the process required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

B. Administration.

The dangerous microbes and pathogens will be known as "select agents and toxins." The select agent and toxin registry will be maintained by the Virginia Department of Health, Office of Epidemiology, Division of Surveillance and Investigation.

C. Reportable agents.

The board declares the select agents and toxins and overlap select agents and toxins outlined in 42 CFR Part 73 to be reportable and adopts it herein by reference including subsequent amendments and editions. The select agents and toxins are to be reportable by the persons enumerated in subsection F of this section.

D. Items to report.

Each report shall be made on a form determined by the department and shall contain the following: name, source and characterization information on select agents and toxins and quantities held; objectives of the work with the agent; location (including building and room) where each select agent or toxin is stored or used; identification information of persons with access to each agent; identification information of the person in charge of each of the agents; and the name, position and identification information of one responsible official as a single point of contact for the organization. The report shall also indicate whether the laboratory is registered with the CDC Select Agent Program and may contain additional information as required by 42 CFR Part 73 or the department.

E. Timing of reports.

Reports shall be made to the department within seven calendar days of submission of an application to the CDC Select Agent Program. By January 31 of every year, laboratories shall provide a written update to the department, which shall include a copy of the federal registration certificate received through the CDC Select Agent Program.

In the event that a select agent or toxin that has previously been reported to the department is destroyed, a copy of federal forms addressing the destruction of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a select agent or toxin, has previously been reported to the department and is subsequently transferred to a facility eligible for receiving the items, a copy of federal forms addressing the transfer of the select agent or toxin must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

In the event of a suspected release, loss, or theft of any select agent or toxin, the responsible official at a laboratory shall make a report to the department immediately by the most rapid means available, preferably by telephone. The rapid report shall be followed up by a written report within seven calendar days and shall include the following information:

1. The name of the biologic agent and any identifying information (e.g., strain or other characterization information);

2. An estimate of the quantity released, lost, or stolen;

3. An estimate of the time during which the release, loss, or theft occurred; and

4. The location (building, room) from or in which the release, loss, or theft occurred. The report may contain additional information as required by 42 CFR Part 73 or the department.

The department shall be notified in writing of any change to information previously submitted to the department. If a new application or an amendment to an existing application is filed with the CDC Select Agent Program, a copy of the application or amendment shall be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

F. Those required to report.

The laboratory director shall be responsible for annual reporting of select agents and toxins to the Virginia Department of Health and for the reporting of any changes within the time periods as specified within these regulations. Such reports shall be made on forms to be determined by the department. Any person making such reports as authorized herein shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*.

G. Exemption from reporting.

A person who detects a select agent or toxin for the purpose of diagnosing a disease, verification, or proficiency testing and either transfers the specimens or isolates containing the select agent or toxin to a facility eligible for receiving them or destroys them on site is not required to make a report except as required by 12VAC5-90-80 and 12VAC5-90-90. Proper destruction of the agent shall take place through autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The transfer or destruction shall occur within seven calendar days after identification of a select agent or toxin used for diagnosis or testing and within 90 calendar days after receipt for proficiency testing.

Any additional exemptions from reporting under 42 CFR Part 73, including subsequent amendments and editions, are also exempt from reporting under this regulation; however, the department shall be notified of the exemption by submitting a copy of federal forms addressing the exemption within seven calendar days of submission to the CDC Select Agent Program.

H. Release of reported information.

Reports submitted to the select agent and toxin registry shall be confidential and shall not be a public record pursuant to the Freedom of Information Act, regardless of submitter. Release of information on select agents or toxins shall be made only by order of the State Health Commissioner to the

CDC and state and federal law-enforcement agencies in any investigation involving the release, theft, or loss of a select agent or toxin required to be reported to the department under this regulation.

Part XIII.

REPORTING OF HEALTHCARE-ASSOCIATED INFECTIONS

12VAC5-90-370. Reporting of healthcare-associated infections.

A. Reportable infections.

Facilities that report data into the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) for the Centers for Medicare and Medicaid Services Hospital Inpatient Quality Reporting Program shall share the data, through the NHSN, with the department.

B. Liability protection and data release.

Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*. Infection rate data may be released to the public by the department upon request. Data shall be aggregated to ensure that no individual patient may be identified.