

Regulations for Disease Reporting and Control

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 individuals 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 reside or may be located.

“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.

~~“Carrier” means a person who, with or without any apparent symptoms of a communicable disease, harbors a specific infectious agent and may serve as a source of infection.~~

“Child care center” means a child day center, child day center system, 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.

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“Commissioner” means the State Health Commissioner, or his duly designated officer or agent, unless stated in a provision of these regulations 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 these regulations, 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 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,

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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 article.

“Condition” means any adverse health event ~~that is not technically a disease~~, 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) indicating 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 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.

“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.

“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.

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

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“Essential needs” means basic human needs for sustenance including but not limited to food, water, 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: 1) 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; 2) known or suspected risk factors for infection; 3) the potential magnitude of the effect of the disease on the health and welfare of the public; and 4) 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 ~~intoxications~~ intoxication, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, *Clostridium perfringens* food poisoning, hepatitis A, and *Escherichia coli* 0157:H7 ~~illness~~ infection.

“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

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levels [(ALT)] greater than [~~seven times the upper limit of normal~~ 400 IU/L]; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done) [~~or HBsAg negative~~]; and (d) ~~antibody to hepatitis C virus (anti-HCV) positive verified by a repeat anti-HCV positive test by EIA and confirmed by a more specific assay or positive by RIBA, nucleic acid test, or anti-HCV by EIA with a signal to cutoff ratio of 3.8 or greater.~~ hepatitis C virus antibody (anti-HCV) screening test positive [verified by an additional more specific assay, e.g., immunoblot (RIBA) or detection of nucleic acid, or by anti-HCV antibody screening test positive] with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay [as defined by CDC, HCV antibody positive by immunoblot (RIBA), 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 [~~seven times the upper limit of normal~~ 400 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.

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“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 an 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).

“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 separation for the period of communicability of infected persons or animals from others in such places and under such conditions as to prevent or limit the direct or indirect transmission of an infectious agent from those infected to those who are susceptible. The means of isolation shall be the least restrictive means appropriate under the facts and circumstances as determined by the commissioner.~~ 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 of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat 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

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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

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local governing body. “Law-enforcement agency” shall include, by order of the Governor, the Virginia National Guard.

“Lead - elevated blood levels” means ~~a child or children 15 years of age and younger~~ with a confirmed blood level greater than or equal to 10 micrograms of lead per deciliter ($\mu\text{g}/\text{dL}$) of whole blood in a child or children 15 years of age and younger, a person older than 15 years of age with a venous blood lead level greater than or equal to 25 $\mu\text{g}/\text{dL}$ in a person older than 15 years of age, or such lower blood lead level as may be recommended for individual intervention by the department or the Centers for Disease Control and Prevention.

“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 possesses a midwife permit issued by the State Health Commissioner.

“Nosocomial outbreak” means any group of illnesses of common etiology occurring in patients of a medical care facility acquired by exposure of those patients to the disease agent while confined in such a facility.

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“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 ~~an occupational health problem~~ a work-related exposure. Such ~~diseases~~ 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 ~~generally, a period of detention for persons or domestic animals that may have been exposed to a reportable, contagious disease for purposes of observation or treatment.~~

- ~~1. Complete quarantine. The formal limitation of freedom of movement of well persons or animals exposed to a reportable disease for a period of time not longer than the longest incubation period of the disease in order to prevent effective contact with the unexposed. The means of complete quarantine shall be the least restrictive means~~

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~~appropriate under the facts and circumstances, pursuant to 12 VAC 5-90-90 E or as determined by the commissioner.~~

- ~~2. Modified quarantine. A selective, partial limitation of freedom of movement of persons or domestic animals, determined on the basis of differences in susceptibility, or danger of disease transmission. Modified quarantine is designed to meet particular situations and includes but is not limited to, the exclusion of children from school and the prohibition or restriction of those exposed to or suffering from a communicable disease from engaging in a particular occupation. The means of modified quarantine shall be the least restrictive means appropriate under the facts and circumstances, pursuant to 12 VAC 5-90-90 E or as determined by the commissioner.~~

- ~~3. Segregation. The separation, for special control or observation, of one or more persons or animals from other persons or animals to facilitate control or surveillance of a reportable disease. The means of segregation shall be the least restrictive means available under the facts and circumstances, as determined by the commissioner. 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 of public health threat and who do not yet show signs or symptoms of infection with the communicable disease of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat to unexposed and uninfected individuals.~~

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“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, and/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.

[“SARS” means severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV) disease.]

“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 parochial school that offers instruction at any level or grade from kindergarten through grade 12; iii) any private or

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parochial nursery school or preschool, or any private or parochial child care center licensed by the Commonwealth; and iv) any preschool handicapped classes or Head Start classes.

“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. ~~For the purpose of this regulation, serology includes the concept that a positive test result is defined as one that is outside the normal range of results as determined by the laboratory performing the test.~~

“Surveillance” means the on-going 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.

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“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, 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 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 to contain tubercle bacilli is unobtainable.~~

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~~“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 established by the commissioner.~~

“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 less than 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.

~~“Tuberculin skin test (TST)” means a test for infection with tubercle bacilli, performed according to the Mantoux method, in which 5 tuberculin units (5TU=0.1cc) of a standardized~~

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~~preparation of purified protein derivative (PPD S) are injected intradermally on the volar surface of the arm and the reaction read as the transverse diameter of the palpable area of induration, recorded in mm of induration. The significance of the measured induration is based on existing national and state guidelines.~~

“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.

~~“Vancomycin resistant *Staphylococcus aureus*” means any *Staphylococcus aureus* culture that demonstrates intermediate or greater resistance to vancomycin.~~

“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, ~~Section~~§ 32.1-35 directs the Board of Health to promulgate regulations specifying

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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.

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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

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~~implementing the quarantine, and isolation, or segregation as required by 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~~ 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, ~~unless otherwise expressly provided by him~~.

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 32.1-71.4 of the *Code of Virginia*.

PART III.**REPORTING OF DISEASE****12 VAC 5-90-80. Reportable Disease List.**

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 12 VAC 5-90-90. Conditions identified by an asterisk (*) require rapid communication to the local health department within 24 hours of suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

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Acquired ~~Immunodeficiency Syndrome~~ immunodeficiency syndrome (AIDS)

Amebiasis

*Anthrax

Arboviral infection (e.g., EEE, LAC, SLE, WNV)

*Botulism

*Brucellosis

~~Campylobacter infection~~ Campylobacteriosis

Chancroid

Chickenpox (Varicella)

Chlamydia trachomatis ~~infections~~ infection

*Cholera

Creutzfeldt-Jakob disease if ~~<55~~ ≤55 years of age

Cryptosporidiosis

Cyclosporiasis

*Diphtheria

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

Ehrlichiosis

Escherichia coli [~~O157:H7 and other enterohemorrhagic *E. coli* infections~~ infection, Shiga toxin-producing]

Giardiasis

Gonorrhea

Granuloma inguinale

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**Haemophilus influenzae* infection, invasive

Hantavirus pulmonary syndrome

Hemolytic uremic syndrome (HUS)

*Hepatitis A (IgM+)

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

Kawasaki syndrome

Lead-elevated blood levels

Legionellosis

Leprosy (Hansen's disease)

Listeriosis

Lyme disease

Lymphogranuloma venereum

Malaria

*Measles (Rubeola)

*Meningococcal ~~infection~~ disease

*Monkeypox

Mumps

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Ophthalmia neonatorum

*Outbreaks, all (including but not limited to foodborne, nosocomial, occupational, toxic substance-related, and waterborne, ~~and other outbreaks~~)

*Pertussis (~~Whooping cough~~)

*Plague

*Poliomyelitis

*Psittacosis

*Q fever

*Rabies, human and animal

Rabies treatment, post-exposure

Rocky Mountain spotted fever

*Rubella (~~German measles~~), including congenital rubella syndrome

Salmonellosis

*Severe ~~Acute Respiratory Syndrome~~ acute respiratory syndrome (SARS)

Shigellosis

*Smallpox (Variola)

Streptococcal disease, Group A, invasive

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

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

Tetanus

Toxic shock syndrome

Toxic substance-related illness

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Trichinosis (Trichinellosis)

*Tuberculosis, active disease

Tuberculosis infection in children ~~ages~~ <4 years of age

*Tularemia

Typhoid fever

~~Typhus~~

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

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

**Vibrio* infection

*Viral hemorrhagic fever

*Yellow ~~Fever~~ fever

Yersiniosis

B. ~~Diseases~~ Conditions reportable by directors of laboratories.

Conditions identified by an asterisk (*) require rapid communication to the local health department within 24 hours of 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 ~~method or serology~~, nucleic acid detection, or serologic results consistent with recent infection

*Anthrax - by culture, antigen detection, or ~~polymerase chain reaction or other~~ nucleic acid amplification method detection

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Arboviral infection - by ~~viral isolation, serology or polymerase chain reaction or other~~ culture, antigen detection, nucleic acid amplification method detection, or serologic results consistent with recent infection

*Botulism - by culture or identification of toxin in ~~stool, serum or gastric aspirate or by culture a~~ clinical specimen

*Brucellosis - by culture, antigen detection, serology or polymerase chain reaction or other nucleic acid ~~amplification method of *Brucella* spp. in a clinical specimen~~ detection, or serologic results consistent with recent infection

~~*Campylobacter* infection~~ Campylobacteriosis - by culture

Chancroid - by culture, antigen detection, or immunofluorescence or polymerase chain reaction or other nucleic acid ~~amplification method~~ detection

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

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

*Cholera - by culture or ~~serology~~ serologic results consistent with recent infection

Creutzfeldt-Jakob disease if <55 years of age - presumptive diagnosis ~~via~~ by histopathology in patients under the age of 55 years of age and under

Cryptosporidiosis - by microscopic examination ~~of stool or biopsy specimens,~~ antigen detection ~~method, immunofluorescent antibody or polymerase chain reaction or other~~ nucleic acid ~~amplification method~~ detection

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Cyclosporiasis - by microscopic examination of stool or nucleic acid detection

*Diphtheria - by culture

Ehrlichiosis - by ~~serology, polymerase chain reaction, other~~ culture, nucleic acid amplification method or culture detection, or serologic results consistent with recent infection

Escherichia coli [O157:H7 ~~and other enterohemorrhagic *E. coli* infections~~ - by isolation of *E. coli* O157:H7, *E. coli* O157, or other Shiga toxin-producing enterohemorrhagic *E. coli* from a clinical specimen. infection, Shiga toxin-producing - by culture of *E. coli* O157 or other Shiga toxin-producing *E. coli*, Shiga toxin detection (e.g., by EIA), or nucleic acid detection]

Giardiasis - by microscopic examination or antigen detection ~~method~~

~~Gonococcal infection~~ Gonorrhea - by ~~culture~~, microscopic examination of a urethral smear specimen (males only), culture, antigen detection, or ~~by~~ nucleic acid detection method

**Haemophilus influenzae* infection, invasive - by culture, ~~immunofluorescence, EIA, or polymerase chain reaction or other~~ antigen detection, or nucleic acid ~~amplification method of~~ detection from a normally sterile site

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

*Hepatitis A - by ~~serology specific for~~ detection of IgM antibodies

Hepatitis B (acute and chronic) - ~~Report either of the following:~~

- ~~1. Serology specific for IgM antibodies~~
- ~~2. HBsAg positive results by~~ detection of HBsAg or IgM antibodies

Hepatitis C (acute and chronic) - by ~~laboratory results that indicate: (i) serum aminotransferase levels greater than seven times the upper limit of normal; (ii) IgM anti-HAV negative; (iii)~~

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~~IgM anti HBc negative (if done) or HBsAg negative; and (iv) antibody to hepatitis C virus (anti HCV) positive verified by a repeat anti HCV positive test by EIA and confirmed by a more specific assay or positive by RIBA, nucleic acid test, or anti HCV by EIA with a signal to cutoff ratio of 3.8 or greater~~ hepatitis C virus antibody (anti-HCV) screening test positive [verified by an additional more specific assay, e.g., immunoblot (RIBA) or detection of nucleic acid, or by anti HCV antibody screening test positive] with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay [as defined by CDC, HCV antibody positive by immunoblot (RIBA), or HCV RNA positive by nucleic acid test]. For all hepatitis C patients, also report [available] results of serum [alanine] aminotransferase [(ALT)], anti-HAV IgM, anti-HBc IgM, and HBsAg.

~~Human immunodeficiency virus (HIV) infection - by laboratory results which indicate the presence of HIV antigen, nucleic acid, or antibodies such as enzyme linked immunosorbent assays positive confirmed with a supplemental test such as the western blot or by rapid tests with confirmation~~ by culture, antigen detection, nucleic acid detection, or detection of antibody confirmed with a supplemental test. For HIV-infected patients, report all results of CD4 and HIV viral load tests.

Influenza – by culture, ~~serology or~~ antigen detection [by direct fluorescent antibody (DFA)] method ~~(report total number per week and by type, if available)~~, or nucleic acid detection, or serologic results consistent with recent infection]

Lead-elevated blood levels - by blood lead level greater than or equal to 10 µg/dL in children ages 0-15 years, or greater than or equal to 25 µg/dL in persons older than 15 years of age

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Legionellosis - by culture, ~~direct fluorescent antibody test, serology, urine antigen detection (including urinary antigen), method or polymerase chain reaction or other nucleic acid amplification method~~ detection, or serologic results consistent with recent infection

Listeriosis - by culture

Malaria - by microscopic examination, antigen detection, or polymerase chain reaction or other nucleic acid amplification method or antigen detection method detection

*Measles (rubeola) - by ~~serology specific for IgM antibodies, paired sera results indicating a significant rise in antibody level, by culture or polymerase chain reaction or other nucleic acid amplification method~~ culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Meningococcal ~~Infection~~ disease - by culture or antigen detection ~~of~~ from a normally sterile site

*Monkeypox - by culture or nucleic acid amplification method or culture detection

Mumps - by ~~serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture~~ culture, nucleic acid detection, or serologic results consistent with recent infection

*Mycobacterial diseases - (See 12 VAC 5-90-225 B) Report any of the following:

1. Acid fast bacilli ~~on smear~~ by microscopic examination;
2. Mycobacterial identification - preliminary and final identification ~~by rapid methodologies and/or by culture or polymerase chain reaction~~ nucleic acid detection;
3. Drug susceptibility test results for *M. tuberculosis*.

*Pertussis - ~~confirmed~~ by culture, antigen detection, or polymerase chain reaction or other nucleic acid amplification method or suspected by direct fluorescent antibody test detection

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*Plague - by culture, ~~or direct fluorescent antibody test~~ antigen detection, nucleic acid detection,
or serologic results consistent with recent infection

*Poliomyelitis - by culture ~~or serology~~

*Psittacosis - by culture, antigen detection, ~~method or polymerase chain reaction or other~~ nucleic
acid ~~amplification method~~ detection, or serologic results consistent with recent infection

*Q fever - ~~by serology, immunofluorescent antibody, polymerase chain reaction or other nucleic~~
~~acid amplification method or enzyme linked immunosorbent assay~~ by culture, antigen
detection, nucleic acid detection, 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

Rocky Mountain spotted fever - by ~~serology, indirect immunofluorescent antibody, enzyme~~
~~immunoassay, polymerase chain reaction or other nucleic acid amplification method or~~
~~immunohistochemical staining~~ culture, antigen detection (including immunohistochemical
staining), nucleic acid detection, or serologic results consistent with recent infection

*Rubella - ~~by serology specific for IgM antibodies or paired sera results indicating a significant~~
~~rise in antibody level or by culture,~~ nucleic acid detection, or serologic results consistent with
recent infection

~~Salmonella infection~~ Salmonellosis - by culture

*Severe ~~Acute Respiratory Syndrome~~ acute respiratory syndrome - by culture, nucleic acid
~~amplification method, serology, or culture~~ detection, or serologic results consistent with
recent infection

~~Shigella infection~~ Shigellosis - by culture

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*Smallpox (variola) - by culture or ~~polymerase chain reaction or other~~ nucleic acid ~~amplification~~ method via reference laboratory detection

Streptococcal disease, Group A, invasive - by culture from a normally sterile 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 ~~serology~~, microscopic examination (including dark field) examination, antigen detection (including direct fluorescent antibody), or equivalent 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

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

*Tularemia - by culture, ~~paired serology, polymerase chain reaction or other~~ antigen detection, nucleic acid amplification method or direct immunofluorescent assay detection, or serologic results consistent with recent infection

*Typhoid fever - by culture

~~Typhus - by immunofluorescent assay, enzyme immunoassay, complement fixation or immunohistochemical staining~~

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

Vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus* infection - by antimicrobial susceptibility testing ~~conducted on culture~~ of a *Staphylococcus aureus* isolate,

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with a vancomycin susceptibility result of intermediate or resistant, cultured from a clinical specimen

**Vibrio* infection - by culture

*Viral hemorrhagic fever - by culture, antigen detection (including immunohistochemical staining), polymerase chain reaction or other nucleic acid amplification method, immunofluorescent assay, complement fixation, virus isolation or enzyme linked immunosorbent assay detection, or serologic results consistent with recent infection

*Yellow fever - by culture, antigen detection, virus isolation, enzyme linked immunosorbent assay, polymerase chain reaction or other nucleic acid amplification method or immunofluorescent assay. 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 within 24 hours by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, pagers, etc.) to the local health director or other professional employee of the department. (These same diseases are also identified by an asterisk (*) in subsection A and, where applicable, subsection B of this section.)

Anthrax

Botulism

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Brucellosis

Cholera

Diphtheria

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

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza deaths in children <18 years of age

Measles (Rubeola)

Meningococcal ~~infection~~ disease

Monkeypox

Outbreaks, all

Pertussis

Plague

Poliomyelitis

Psittacosis

Q fever

Rabies, human and animal

Rubella

Severe ~~Acute Respiratory Syndrome~~ acute respiratory syndrome (SARS)

Smallpox (Variola)

Syphilis, primary and secondary

Tuberculosis, active disease

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Tularemia

Typhoid fever

Unusual occurrence of disease of public health concern

Vaccinia, disease or adverse event

Vibrio infection

Viral hemorrhagic fever

Yellow fever

~~[D. Diseases Disease to be reported by number of cases:~~

~~The following disease in the list of reportable diseases shall be reported as number of cases only:~~

~~—Influenza (by type, if available)]~~

~~E. Human immunodeficiency virus (HIV) infection.~~

~~Every physician practicing in this Commonwealth shall report to the local health department any patient of his who has tested positive for human immunodeficiency virus (HIV). Every person in charge of a medical care facility shall report the occurrence in or admission to the facility of a patient with HIV infection unless there is evidence that the occurrence has been reported by a physician. When such a report is made, it shall include the information required in 12 VAC 5-90-90 A. Only individuals who have laboratory results which indicate the presence of HIV antigen, nucleic acid, or antibodies {such as at least two enzyme linked immunosorbent assays (done in duplicate at the same time or singly at different times), and a supplemental test such as the western blot or by rapid tests with confirmation} are considered to have HIV infection.~~

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F ~~E. D.~~ 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 by rapid communication as in subsection C of this section.

G ~~E. 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 by the most rapid means available.

H ~~G. E.~~ 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 by the most rapid means available. 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*.

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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, ~~sex~~, race, sex, and pregnancy status for females; name of disease diagnosed or suspected; ~~and~~ ; the date of onset of illness; 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). ~~The pregnancy status of females who test positive for HBsAg should be reported, 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 to be provided by the department (Form Epi-1), a computer generated printout containing the data items requested on Form Epi-1, or a Centers for Disease Control and Prevention (CDC) surveillance form that provides the same information and shall be made within three days of the suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12 VAC 5-90-80 C. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.

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Pursuant to § 32.1-49.1 of the *Code of Virginia*, additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X for details on these requirements.

B. Directors of laboratories.

Any person who is in charge of a laboratory conducting business in the Commonwealth shall report any laboratory examination of any clinical specimen ~~derived from the human body~~, 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 12 VAC 5-90-80 B₂.

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 ~~address~~ pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, ~~and address, and telephone number~~ of the physician ~~or~~ and medical facility for whom the examination was made. When the influenza virus is isolated, the type should be reported, if available. ~~The pregnancy status of females who test positive for HBsAg should be reported, if available.~~ Reports shall be made within three days of identification of evidence of disease, except that those identified by an asterisk shall be reported within 24 hours by the most rapid means available, 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

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department. 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 ~~shall fulfill its responsibility to report~~ identifying evidence of anthrax, cholera, diphtheria, *E. coli* ~~O157:H7~~ O157 infection, invasive *H. influenzae* infection, *Listeria listeriosis*, meningococcal ~~infection~~ disease, [~~*Mycobacterium tuberculosis* complex~~ (see 12 VAC 5-90-225);] pertussis, plague, poliomyelitis, ~~*Salmonella* infection~~ salmonellosis, ~~*Shigella* infection~~ shigellosis, invasive Group A streptococcal ~~infection~~ disease, [yersiniosis,] and other diseases as may be requested by the health department ~~by both notifying~~ , shall notify the health department of the positive culture and ~~submitting~~ submit the initial ~~culture~~ isolate to the Virginia Division of Consolidated Laboratory Services (DCLS). Stool specimens that test positive for Shiga toxin shall be submitted to DCLS for organism identification. [A laboratory identifying *Mycobacterium tuberculosis* complex (see 12 VAC 5-90-225) shall submit a representative and viable sample of the initial culture to DCLS or other laboratory designated by the Board to receive such specimen.] All specimens must be identified with the patient and physician information required in this subsection. ~~At times, other laboratories may also be requested to submit specimens to the Virginia Division of Consolidated Laboratory Services.~~

Laboratories operating within a medical care facility shall be considered to be in compliance with the requirement to notify the health department when the director of that medical care facility assumes the reporting responsibility; however, laboratories are still required to submit isolates to DCLS [or other designated laboratory] as noted above.

C. Person[s] in charge of a medical care facility.

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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 12 VAC 5-90-80 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 reports shall contain the patient's name, address, age, date of birth, ~~address, sex,~~ race, sex, and pregnancy status for females; name of disease being reported; 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). ~~The pregnancy status of females who test positive for HBsAg should be reported, if available.~~ Reports shall be made within three days of the suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12 VAC 5-90-80 C and shall be made on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a Centers for Disease Control and Prevention (CDC) 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. Person[s] in charge of a school, child care center, or summer camp.

Any person in charge of a school, child care center, or summer camp shall report immediately to the local health department the presence or suspected presence in his school[, or] child care

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center[, or summer camp] of children who have common symptoms suggesting an epidemic or outbreak situation. [Such persons may notify the local health department of individual cases of communicable diseases that occur in their facilities.] Any person so reporting shall be immune from liability as provided by § 32.1-38 of the *Code of Virginia*.

E. Local health director[s].

The local health director shall forward ~~within three days of receipt to the Office of Epidemiology of the State Health Department~~ 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 by telecommunication if the disease is one requiring rapid communication, as required in 12 VAC 5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office of Epidemiology within ~~seven~~ 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.

~~When notified about a disease specified in 12 VAC 5-90-80, the local health department shall perform contact tracing for HIV infection, infectious syphilis, and active tuberculosis disease and may perform contact tracing for the other diseases if deemed necessary to protect the public health. The local health director shall have the responsibility to accomplish contact tracing, by either having patients inform their potential contacts directly or through obtaining pertinent information such as names, descriptions, and addresses to enable the health department staff to inform the contacts. 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~~

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~~case shall names of informants or infected persons 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. He shall determine, in consultation with the Director of the Office of Epidemiology and the commissioner, if further investigation is required and if complete or modified quarantine will be necessary.~~

~~Modified quarantine shall apply to situations in which the local health director on the scene would be best able to judge the potential threat of disease transmission. Such situations shall include, but are not limited to, the temporary exclusion of a child with a communicable disease from school and the temporary prohibition or restriction of any individual(s), exposed to or suffering from a communicable disease, from engaging in an occupation such as foodhandling that may pose a threat to the public. Modified quarantine shall also include 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. In these situations, the local health director may be authorized as the commissioner's designee to order the least restrictive means of modified quarantine.~~

~~Where modified quarantine is deemed to be insufficient and complete quarantine or isolation is necessary to protect the public health, the local health director, in consultation with the Director of the Office of Epidemiology, shall recommend to the commissioner that a quarantine order or isolation order be issued.~~

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F. Person[s] 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, ~~adult care residence~~ 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

Monkeypox

Rabies

Smallpox

Syphilis, infectious

Tuberculosis, active disease

Vaccinia, disease or adverse event

Viral hemorrhagic fever

G. Employees, applicants, and persons in charge of food establishments.

12 VAC 5-421-80 of the Food Regulations requires a food employee or applicant to notify the person in charge of the food establishment when diagnosed with certain diseases that are

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transmissible through food. 12 VAC 5-421-120 requires the person in charge of the food establishment to notify the health department. Refer to the appropriate sections of the *Virginia Administrative Code* for further guidance and clarification regarding these reporting requirements.

PART IV.**CONTROL OF DISEASE****12 VAC 5-90-100. Methods.**

~~The "Methods of Control" sections of the 17th Edition of the *Control of Communicable Diseases Manual* (2000) published by the American Public Health Association shall be complied with by~~
The board and commissioner shall use appropriate disease control measures to manage in
controlling the diseases listed in 12 VAC 5-90-80 A, including but not limited to those described
in the "Methods of Control" sections of the 18th Edition of the *Control of Communicable*
Diseases Manual (2004) published by the American Public Health Association~~except to the~~
~~extent that the requirements and recommendations therein are outdated, inappropriate,~~
~~inadequate, or otherwise inapplicable.~~ 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 12 VAC 5-90-80, the local health director or his
designee shall have the authority and responsibility to perform contact tracing for HIV infection,
infectious syphilis, and active tuberculosis disease and may perform contact tracing 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

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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 and/or isolation 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 which places others at risk for infection with the communicable disease of public health significance, in accordance with the provisions of Article 3.01 (§ 32.1-48.02 et seq.) 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, or the temporary prohibition or restriction of any individual or individuals with a communicable disease from engaging in activities that may pose a risk to the health of others, such as using public transportation or performing an occupation such as foodhandling or providing healthcare.

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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 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 and/or quarantine under Article 3.02 (§ 32.1-48.05 et seq.) 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 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, and
2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) of the Code of Virginia to be insufficient, or the individual or individuals have failed or

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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.

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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 when possible, 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, to the affected individual or individuals in person to the extent practicable. If,

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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 issue an emergency detention order requiring such individual or individuals 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, 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.

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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 to an affected area, existing emergency protocols pursuant to § 44-146.13 et seq. 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 § 32.1-48.013 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.

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. In order for an affected area to be isolated, the Governor must declare a state of emergency for the affected area.

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If an order of isolation is issued for an affected area, 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/quarantine 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 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 the *Code of Virginia* and may order a complete or modified quarantine of any individual or individuals upon a determination that:

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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, and
2. Exceptional circumstances render the procedures of Article 3.01 (§ 32.1-48.01 et seq.) 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.

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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 when possible, 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, 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

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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 issue an emergency detention order requiring 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, 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

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disease of public health threat then 12-VAC-90-103 (Isolation for Communicable Disease of Public Health Threat) 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 to an affected area, existing emergency protocols pursuant to § 44-146.13 et seq. 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 § 32.1-48.010 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 determined to no longer be 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.

J. Affected area

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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 isolation, 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 the affected area.

PART V.**IMMUNIZATION OF CHILDREN**

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12 VAC 5-90-110. Dosage and Age Requirements for Immunizations; Obtaining Immunizations.

A. Every child in Virginia shall be immunized against the following diseases by receiving the specified number of doses of vaccine by the specified ages, unless replaced by a revised schedule of the U.S. Public Health Service:

1. Diphtheria, Tetanus, and Pertussis (~~Whooping cough~~) Vaccine – three doses by one year of age of toxoids of diphtheria and tetanus, combined with pertussis vaccine with the remaining two doses administered in accordance with the most recent schedule of the American Academy of Pediatrics or the U.S. Public Health Service.
2. Poliomyelitis Vaccine, trivalent type - three doses of inactivated poliomyelitis vaccine, preferably by one year of age and no later than 18 months of age. Attenuated (live virus) oral polio ~~virus~~ vaccine may be used if the attending physician feels it is clinically appropriate for a given patient.
3. Measles (Rubeola) Vaccine - one dose of further attenuated (live virus) measles vaccine between 12-15 months of age and no later than two years of age. A second dose shall also be required at the time of initial entry to school. For those children who did not receive a second dose at initial school entry, a second dose shall be required at the time of entry to grade six.
4. Rubella (~~German measles~~) Vaccine – one dose of attenuated (live virus) rubella ~~virus~~ vaccine between 12-15 months of age and no later than two years of age.
5. Mumps Vaccine - one dose of ~~mumps virus vaccine~~ attenuated (live virus) mumps vaccine between 12-15 months of age and no later than two years of age.

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6. *Haemophilus influenzae* type b (Hib) Vaccine - a maximum of four doses of Hib vaccine for children up to 30 months of age as appropriate for the child's age and in accordance with current recommendations of either the American Academy of Pediatrics or the U.S. Public Health Service.
7. Hepatitis B Vaccine – three doses by 12 months of age and no later than 18 months of age. For children not receiving three doses ~~between 12-18~~ by 18 months of age, three doses will be required at initial school entry for all children born on or after January 1, 1994. Since July 1 2001, all children who have not received a complete series of hepatitis B vaccine are required to receive such immunization prior to entering and at entry into the sixth grade.
8. Varicella (Chickenpox) Vaccine - one dose of varicella vaccine between 12-18 months of age. For those children who did not receive a dose of vaccine between 12-18 months of age, a dose will be required at initial school entry.

B. The required immunizations may be obtained from a physician licensed to practice medicine or from the local health department.

PART VI.**VENEREAL DISEASE****12 VAC 5-90-130. Prenatal Testing.**

Every physician attending a pregnant ~~woman~~ patient during gestation shall examine and test such ~~woman~~ patient for syphilis and hepatitis B surface antigen (HBsAg) 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 ~~women~~ patients who are at higher risk for

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these diseases. Persons at higher risk for syphilis include those who have had multiple sexual partners within the previous year and those with any prior history of a sexually transmitted disease. 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 advise every pregnant patient of the value of testing for human immunodeficiency virus (HIV) infection and shall request of each pregnant patient consent to such testing. The confidentiality provisions of § 32.1-36.1 of the Code of Virginia, the informed consent stipulations, 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. 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 Centers for Disease Control and Prevention recommendations for HIV-positive pregnant patients. Any pregnant patient shall have the right to refuse consent to testing for HIV infection and any recommended treatment. Documentation of such refusal shall be maintained in the patient's medical record. Every physician should also examine and test a pregnant ~~woman~~ patient for any sexually transmitted disease as clinically indicated.

PART VIII.**CANCER REPORTING****12 VAC 5-90-160. Reportable Cancers and Tumors.**

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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~~ in situ of the cervix is not reportable.

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, ~~and~~ 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

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screening information; and name, ~~and~~ 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, ~~and~~ 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 outpatient, who also have one of the following conditions:
 - (1) HIV infection

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- (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 *M. 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 drug susceptibility tests performed on cultures positive for any member of the *M. tuberculosis* complex.~~ In order to ensure susceptibility testing, laboratories 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 (DCLS) [or other laboratory designated by the Board to receive such specimen]. This requirement may be fulfilled by the submission of a report of antimicrobial drug susceptibility testing performed on the specimen. The intention to file a written report *in lieu* of sample submission shall be communicated by the laboratory at the time the finding of a positive culture is initially communicated.

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5. ~~For each patient in whom one or more cultures are positive for any member of the *M. tuberculosis* complex, the submission of a viable, representative sample of at least the initial culture to the Virginia Division of Consolidated Laboratory Services for additional testing is encouraged.~~ Laboratories which submit a written susceptibility report *in lieu* of sample submission are still strongly encouraged to submit a viable, representative sample for each patient in whom one or more cultures are positive for any member of the *M. tuberculosis* complex for additional testing, if needed.

PART XI.**HUMAN IMMUNODEFICIENCY VIRUS (HIV) TESTING OF GAMETE DONORS****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 ~~one hundred eighty (180)~~ 180 days following donation and used only if the donor tests negative for serum antibodies for HIV-1 and HIV-2 on enzyme-linked ~~immuno~~immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least ~~one hundred eighty (180)~~ 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 ~~immuno~~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

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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 ~~immunoassay~~ immunosorbent assay or blood HIV-1 and HIV-2 by polymerase chain reaction at least ~~one hundred eighty (180)~~ 180 days after donation.

PART XII.**REPORTING OF DANGEROUS MICROBES AND PATHOGENS.****12 VAC 5-90-280. 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.

~~“Select agent or toxin” or “select agent and toxin” means all those biological agents or toxins as defined below:~~

- ~~1. Health and Human Services (HHS) select agents and toxins, as outlined in 42 CFR 73.4;~~
- ~~2. HHS overlap select agents and toxins, as outlined in 42 CFR 73.5.~~

“CDC” means the Centers for Disease Control and Prevention of the Department of Health and Human Services.

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“Diagnosis” means the analysis of specimens for the purpose of identifying or confirming the presence 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.

~~“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.~~

“Select agent or toxin” or “select agent and toxin” means all those biological agents or toxins as defined by federal regulations, including:

1. Health and Human Services (HHS) select agents and toxins, as outlined in 42 CFR 73.4
2. HHS overlap select agents and toxins, as outlined in 42 CFR 73.5.

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“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 ~~their~~ 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.

12 VAC 5-90-330. Timing of Reports.

Initial reports shall be made by October 26, 2004. Thereafter, 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 ~~a~~ 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

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transfer of a 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 within 24 hours by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, pagers, etc.) 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 must be notified in writing of any changes 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 must be submitted to the department within seven calendar days of submission to the CDC Select Agent Program.

12 VAC 5-90-350. 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 onsite is not required to make a

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report. Proper destruction of the agent must take place through ~~auto-claving~~ autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation. The transfer or destruction must 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 73.6, including subsequent amendments and editions, are also exempt from reporting under this regulation; however, the department must 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.

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12 VAC 5-90-360. 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. Release of information on select agents or toxins shall be made only by order of the State Health Commissioner to the ~~Centers for Disease Control and Prevention~~ 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.