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:

"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 ~~§63.1-195~~ §63.2-100 of the *Code of Virginia*, or a similar place providing day care of children by such other name as may be applied.

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

"Commissioner" means the State Health Commissioner, his duly designated officer or agent.

"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.

"Condition" means any adverse health event that is not technically a disease, such as an infection, a syndrome, or procedure indicating 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.

"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.

"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, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, *Clostridium perfringens* food poisoning, hepatitis A, and *Escherichia coli* 0157:H7 illness.

~~"Hepatitis C, acute" means the case meets the following criteria: i) discrete onset of illness; ii) jaundice or serum aminotransferase levels greater than 2.5 times the upper normal limit; iii) test negative for hepatitis A and hepatitis B; and iv) antibody to hepatitis (anti-HCV) verified by a supplemental test. Persons who have chronic hepatitis or are anti-HCV positive should not be reported unless they have evidence of an acute illness compatible with viral hepatitis and other causes of acute hepatitis have been excluded~~.

"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: i) serum aminotransferase levels greater than 7 times the upper limit of normal; and ii) IgM anti-HAV negative; and iii) 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, chronic" means that laboratory criteria ii), iii) and iv) listed above for an acute case are met but clinical symptoms of acute viral hepatitis are not present and serum aminotransferase levels do not exceed seven times the upper limit of normal. This category will include cases that may be acutely infected but not symptomatic.

~~"Immunization" means a procedure which renders an individual less susceptible to the pathologic effects of a disease or provides a measure of protection against the disease (e.g., inoculation, vaccination).~~

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

"Independent pathology laboratory" means a non-hospital 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.

"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, ~~and~~ 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.

"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.

"Lead - elevated blood levels" means a child or children 15 years of age and younger with a confirmed ~~venous~~ blood level greater than or equal to 10 micrograms of lead per deciliter (μg/dL) of whole blood, a person older than 15 years of age with a venous blood lead level greater than or equal to 25 μg/dL, or such lower blood lead level as may be recommended for individual intervention by the Department or the ~~United States Department of Health and Human Services, Public Health Service,~~ Centers for Disease Control and Prevention.

"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.

"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. Such diseases include but are not limited to silicosis, asbestosis, byssinosis, 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 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.

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

“School" means i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth; ii) any private or parochial school that offers instruction at any level or grade from kindergarten through grade 12; iii) any private or 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 which 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.

"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.

"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 communicable 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.

"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 infection in children age < 4 years" means a significant reaction resulting from a 0.1 ml intradermal injection of a 5 tuberculin unit (TU) dose of PPD-S (Mantoux tuberculin skin test) with no chest x-ray or clinical indication of active tuberculosis disease in children from birth up to their fourth birthday. A significant reaction is 5 mm induration in known contacts to tuberculosis disease and HIV seropositive persons and 10 mm in all others.~~

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

"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 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 signifance of the measured induration is based on existing national and state guidelines.

"Vaccinia, disease or adverse event" means 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 5-90-40. 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.

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.

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 ~~department~~ Office of Epidemiology. In cooperation with the commissioner, he is responsible for instituting measures for disease control, which may include quarantine, isolation, or segregation as required by 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 coordinating the investigation of those diseases with the local health director, and for providing direct assistance where necessary. The Director of the Office of Epidemiology acts as the commissioner's designee in reviewing reports and investigations of diseases and recommendations by local health directors for quarantine or isolation. However, authority to order quarantine or isolation resides solely with the commissioner, unless otherwise expressly provided by him.

E. Confidentiality - 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~~, 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 listed in capital and bold letters require rapid communication to the local health department within 24 hours of suspicion or confirmation, as defined in subsection B of this section~~:~~. Other conditions should be reported within 3 days of suspected or confirmed diagnosis.

Acquired immunodeficiency syndrome (AIDS)
Amebiasis
ANTHRAX
Arboviral infection (e.g., EEE, LAC, SLE, WNV)
BOTULISM
~~Brucellosis~~ **BRUCELLOSIS**
Campylobacter infection
Chancroid
Chickenpox
Chlamydia trachomatis infection
CHOLERA
Creutzfeldt-Jakob disease if <55 years of age
Cryptosporidiosis
Cyclosporiasis
DIPHTHERIA
DISEASE CAUSED BY AN AGENT THAT MAY HAVE BEEN USED AS A WEAPON
Ehrlichiosis
Escherichia coli O157:H7 and other enterohemorrhagic *E. coli* infections
Giardiasis
Gonorrhea
Granuloma inguinale
***HAEMOPHILUS INFLUENZAE* INFECTION, INVASIVE**
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS)
HEPATITIS A (IgM+)
Hepatitis B~~:~~ (acute and chronic)
~~Acute disease (IgM+)~~

~~HbsAg positive pregnant woman~~
Hepatitis C (acute and chronic)
Hepatitis, Other Acute Viral
Human immunodeficiency virus (HIV) infection
Influenza
Kawasaki syndrome
Lead - elevated blood levels
Legionellosis
Leprosy (Hansen disease)
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
MEASLES (Rubeola)
MENINGOCOCCAL INFECTION
Mumps
Ophthalmia neonatorum
OUTBREAKS, ALL (including foodborne, nosocomial, occupational, toxic substance-related, waterborne, and other outbreaks)
PERTUSSIS (Whooping cough)
PLAGUE
POLIOMYELITIS
PSITTACOSIS
~~Q fever~~ **Q FEVER**
RABIES, HUMAN AND ANIMAL
Rabies treatment, post-exposure
Rocky Mountain spotted fever
Rubella (German measles), including congenital rubella syndrome
Salmonellosis
Shigellosis
~~Smallpox~~ **SMALLPOX (VARIOLA)**
Streptococcal disease, Group A, invasive
Streptococcus pneumoniae, invasive if <5 years of age
Syphilis (report **PRIMARY and SECONDARY** syphilis by rapid means)
Tetanus
Toxic shock syndrome
Toxic substance-related illness
Trichinosis (Trichinellosis)
TUBERCULOSIS, ACTIVE DISEASE
Tuberculosis infection in children age <4 years ~~(Mantoux tuberculin skin test reaction ≥ 10 mm)~~
~~Tularemia~~ **TULAREMIA**
Typhoid fever
Typhus
~~Unusual occurrence of disease of public health concern~~ **UNUSUAL OCCURRENCE OF DISEASE OF PUBLIC HEALTH CONCERN**

VACCINIA, DISEASE OR ADVERSE EVENT
Vancomycin-resistant *Staphylococcus aureus*
~~*Vibrio* infection~~ ***VIBRIO* INFECTION**
~~Viral hemorrhagic fever~~ **VIRAL HEMORRHAGIC FEVER**
YELLOW FEVER

B. Diseases Reportable by Directors of Laboratories.

Amebiasis - by microscopic examination, ~~or~~ antigen detection method or serology

ANTHRAX - by culture or polymerase chain reaction or other nucleic acid amplification method

Arboviral infection - by viral isolation, ~~or~~ serology or polymerase chain reaction or other nucleic acid amplification method

BOTULISM - by identification of toxin in stool, ~~or~~ serum or gastric aspirate or by culture

~~Brucellosis~~ **BRUCELLOSIS** - by culture, ~~or~~ serology or ~~immunofluorescence~~ polymerase chain reaction or other nucleic acid amplification method of *Brucella* spp. in a clinical specimen

Campylobacter infection - by culture

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

Chickenpox - by culture or serology

Chlamydia trachomatis infection - by culture or by antigen or nucleic acid detection methods

CHOLERA - by culture or serology

Creutzfeldt-Jakob disease - presumptive diagnosis via histopathology in patients 55 years of age and under

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

Cyclosporiasis - by microscopic examination of stool

DIPHTHERIA - by culture ~~or histopathologic diagnosis~~

Ehrlichiosis- by serology, polymerase chain reaction, other nucleic acid amplification method or culture

Escherichia coli O157:H7 - by isolation of *E. coli* O157:H7, *E. coli* O157, or other ~~enterohemorrhagic *E. coli* from a specimen or isolation of~~ Shiga toxin-producing enterohemorrhagic *E. coli* ~~O157 nonmotile (unable to detect flagellar factor)~~ from a clinical specimen.

Giardiasis - by microscopic examination or antigen detection method

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

HAEMOPHILUS INFLUENZAE **INFECTION** - by culture, immunofluorescence, EIA, or polymerase chain reaction or other nucleic acid amplification method of a normally sterile site

HEPATITIS A - by serology specific for IgM antibodies

Hepatitis B - ~~by serology specific for IgM antibodies~~ Report either of the following:

1. Serology specific for IgM antibodies
2. HBsAg positive results ~~in a female age 15-44 years~~

Hepatitis C – by laboratory results which indicate: i) serum aminotransferase levels greater than 7 times the upper limit of normal; and ii) IgM anti-HAV negative; and iii) 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.

Human immunodeficiency virus (HIV) infection - by 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}

Influenza - by culture, ~~or~~ serology or antigen detection method (report total number per week and by type, if available)

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

Legionellosis - by culture, direct fluorescent antibody test, serology, urine antigen detection method or polymerase chain reaction or other nucleic acid amplification method

Listeriosis - by culture

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

MEASLES - by serology specific for IgM antibodies, ~~or~~ paired sera results indicating a significant rise in antibody level, ~~or~~ by culture or polymerase chain reaction or other nucleic acid amplification method

MENINGOCOCCAL INFECTION – by culture or antigen detection of a normally sterile site

Mumps - by serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture

MYCOBACTERIAL DISEASES – (See 12 VAC 5-90-220 B.) Report any of the following:
1. Acid fast bacilli - on smear
2. Mycobacterial identification - preliminary identification by rapid methodologies and/or by culture or polymerase chain reaction
3. Drug susceptibility test results for *M. tuberculosis*.

PERTUSSIS - confirmed by culture or polymerase chain reaction or other nucleic acid amplification method or suspected by direct fluorescent antibody test

PLAGUE - by culture or direct fluorescent antibody test

POLIOMYELITIS - by culture or serology

PSITTACOSIS – by culture, antigen detection method or polymerase chain reaction or other nucleic acid amplification method

Q FEVER – by serology, immunofluorescent antibody, polymerase chain reaction or other nucleic acid amplification method or enzyme linked immunosorbent assay

RABIES, ~~IN~~ HUMAN AND ANIMALS~~S~~ - by direct fluorescent antibody test

Rocky Mountain spotted fever – by serology, indirect immunofluorescent antibody, enzyme immunoassay, polymerase chain reaction or other nucleic acid amplification method or immunohistochemical staining

Rubella - by serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture

Salmonella infection - by culture

Shigella infection - by culture

SMALLPOX (VARIOLA) – by culture or polymerase chain reaction or other nucleic acid amplification method via reference laboratory

Streptococcal disease, Group A - by culture from a normally sterile site

Streptococcus pneumoniae, invasive – by culture from a normally sterile site in a child under the age of five years

SYPHILIS - by serology, ~~or~~ dark field examination, direct fluorescent antibody, or equivalent methods

Trichinosis - by serology or microscopic examination of a muscle biopsy

TULAREMIA – by culture, paired serology, polymerase chain reaction or other nucleic acid amplification method or direct immunofluorescent assay

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

VACCINIA – by polymerase chain reaction or other nucleic acid amplification method or electron microscopy

Vancomycin-resistant *Staphylococcus aureus* - by antimicrobial susceptibility testing conducted on culture

~~*Vibrio* infection~~ ***VIBRIO* INFECTION** - by culture

VIRAL HEMORRHAGIC FEVER - by polymerase chain reaction or other nucleic acid amplification method, immunofluorescent assay, complement fixation, virus isolation or enzyme linked immunosorbent assay

YELLOW FEVER – by virus isolation, enzyme linked immunosorbent assay, polymerase chain reaction or other nucleic acid amplification method or immunofluorescent assay.

~~B.~~ 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 ~~and in capital and bold letters in subsection A of this section and 12 VAC 5-90-90 B~~, shall be made within 24 hours by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, ~~telegraph, teletype,~~ pagers, etc.) to the local health director or other professional employee of the department. (These same diseases are also listed in capital and bold letters in subsection A of this section and 12 VAC 5-90-90 B.)

Anthrax
Botulism
Brucellosis
Cholera
Diphtheria
Disease caused by an agent that may have been used as a weapon
Haemophilus influenzae infection, invasive
Hepatitis A
Measles (Rubeola)
Meningococcal infection
Outbreaks, all
Pertussis
Plague
Poliomyelitis
Psittacosis
Q fever
Rabies, ~~in man~~ human and animal~~s~~
Smallpox (Variola)
Syphilis, primary and secondary
Tuberculosis, active disease
Tularemia
Unusual occurrence of disease of public health concern
Vaccinia, disease or adverse event
Vibrio infection
Viral hemorrhagic fever
Yellow fever

~~C.~~ D. Diseases 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)

~~D.~~ 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.

~~E.~~ F. Toxic Substance-Related ~~Diseases or~~ Illnesses.

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

If such ~~disease or~~ illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such ~~disease or~~ illness shall be by rapid communication as in subsection B of this section.

~~F.~~ G. 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.

~~G.~~ H. 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 temporary 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 of Health for special surveillance or other epidemiological studies shall be immune from liability as provided by §32.1-38 of the *Code of Virginia*.

~~H. Contact Tracing.~~

~~When notified about a disease specified in subsection A of this section, the local health department shall perform contact tracing for HIV infection, infectious syphilis, and tuberculosis 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 case shall names of informants or infected persons be revealed to contacts by the health department. All information obtained shall be kept strictly confidential.~~

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, ~~or~~ date of birth ~~or both~~, sex, race, name of disease diagnosed or suspected, and the date of onset of illness, 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. ~~Provider organizations, such as health maintenance organizations, may assume the responsibility for reporting on behalf of their member physicians.~~ 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 (Epi-1), a computer generated ~~facsimile of~~ 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 ~~seven~~ three days of the ~~identification~~ suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12 VAC 5-90-80. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the Department.

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 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 ~~below~~ in 12 VAC 5-90-80.B.:

~~Amebiasis - by microscopic examination or antigen detection method or serology~~

~~**ANTHRAX** - by culture~~

~~Arboviral infection - by viral isolation or serology~~

~~**BOTULISM** - by identification of toxin in stool or serum or by culture~~

~~Brucellosis - by culture or serology or immunofluorescence of of *Brucella* spp. in a clinical specimen~~

~~*Campylobacter* infection - by culture~~

~~Chancroid - by culture~~

~~*Chlamydia trachomatis* infection - by culture or by antigen or nucleic acid detection methods~~

CHOLERA - by culture

Cryptosporidiosis - by microscopic examination of stool or biopsy specimens or by antigen detection method

Cyclosporiasis - by microscopic examination of stool

DIPHTHERIA - by culture or histopathologic diagnosis

Escherichia coli O157:H7 - by isolation of *E. coli* O157:H7 or other enterohemorrhagic *E. coli* from a specimen or isolation of Shiga toxin-producing *E. coli* O157 nonmotile (unable to detect flagellar factor) from a clinical specimen.

Giardiasis - by microscopic examination or antigen detection method

Gonococcal infection - by culture or microscopic examination or by antigen or nucleic acid detection method

HAEMOPHILUS INFLUENZAE INFECTION - by culture or polymerase chain reaction of a normally sterile site

HEPATITIS A - by serology specific for IgM antibodies

Hepatitis B - by serology specific for IgM antibodies

Human immunodeficiency virus (HIV) infection - by 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}

Influenza - by culture or serology

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

Legionellosis - by culture, direct fluorescent antibody test, serology, urine antigen detection method or polymerase chain reaction

Listeriosis - by culture

Malaria - by microscopic examination or polymerase chain reaction

MEASLES - by serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture

~~**MENINGOCOCCAL INFECTION** – by culture of a normally sterile site~~

~~Mumps - by serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture~~

~~**MYCOBACTERIAL DISEASES** – Report any of the following:~~
~~1. Acid fast bacilli - on smear~~
~~2. Mycobacterial identification - preliminary identification by rapid methodologies and/or by culture~~
~~**4.** Drug susceptibility test results for *M. tuberculosis*~~

~~**PERTUSSIS** - confirmed by culture or polymerase chain reaction or suspected by direct fluorescent antibody test~~

~~**PLAGUE** - by culture or direct fluorescent antibody test~~

~~**POLIOMYELITIS** - by culture or serology~~

~~**RABIES IN ANIMALS** - by direct fluorescent antibody test~~

~~Rubella - by serology specific for IgM antibodies or paired sera results indicating a significant rise in antibody level or by culture~~

~~*Salmonella* infection - by culture~~

~~*Shigella* infection - by culture~~

~~Streptococcal disease, Group A - by culture from a normally sterile site~~

~~**SYPHILIS** - by serology or dark field examination~~

~~Trichinosis - by serology or microscopic examination of a muscle biopsy~~

~~Vancomycin-resistant *Staphylococcus aureus* - by antimicrobial susceptibility testing conducted on culture~~

~~*Vibrio* infection – by culture~~

Each report shall give the source of the specimen and the laboratory method and result; the name, age~~,~~ ~~or~~ date of birth ~~or both~~, race, sex, and address of the person from whom the specimen was obtained; and the name and address of the physician or 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 ~~seven~~ three days of identification of evidence of disease,

except that those listed in capital and bold letters 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 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 ~~operating within a medical care facility~~ shall fulfill its responsibility to report anthrax, cholera, diphtheria, *E. coli* O157:H7, *H. influenzae* infection, Listeria, meningococcal infection, *Mycobacterium tuberculosis* (see 12 VAC 5-90-220), pertussis, plague, poliomyelitis, *Salmonella* infection, *Shigella* infection, invasive Group A streptococcal infection, and other diseases as may be requested by the health department by both notifying the health department of the positive culture and submitting the initial culture 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 ~~The culture~~ 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 report to the health department when the director of that medical care facility assumes the reporting responsibility.

C. Person in Charge of a Medical Care Facility.

Any person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 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, age, ~~or~~ date of birth ~~or both~~, address, sex, race, 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 ~~seven~~ three days of the ~~identification~~ suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12 VAC 5-90-80 and shall be made on Form Epi-1, a computer generated ~~facsimile of~~ 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 in Charge of a School, ~~or~~ Child Care Center, or Summer Camp.

Any person in charge of a school, ~~or~~ 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 center of children who have common symptoms suggesting an epidemic or outbreak situation. Any person so reporting shall be immune from liability as provided by §32.1-38 of the *Code of Virginia*.

E. Local Health Director.

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

F. Persons in Charge of Hospitals, Nursing Facilities or Nursing Homes, ~~Adult Care Residences~~ Assisted Living Facility, 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, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

Creutzfeldt-Jakob disease
Human immunodeficiency virus infection
Hepatitis B
Hepatitis C
Rabies
Smallpox
~~Infectious syphilis~~ 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 require a food employee or applicant to notify the person in charge of the food establishment when diagnosed with certain diseases that are 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. The "Methods of Control" sections of the ~~Sixteenth~~ most current Edition of the *Control of Communicable Diseases Manual* ~~(1995)~~ published by the American Public Health Association shall be complied with by the board and commissioner in controlling the diseases listed in 12 VAC 5-90-80 A, 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.

Part V.

IMMUNIZATION OF CHILDREN

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 - ~~four~~ three doses by ~~18 months~~ 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 ~~by age 18 months~~ of ~~attenuated (live) trivalent oral polio virus vaccine or~~ inactivated poliomyelitis vaccine ~~or combination~~, 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 ~~at 12-15 months of age~~ of further attenuated (live) measles ~~virus~~ 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 ~~at 12-15 months of age~~ of attenuated (live) rubella virus vaccine between 12-15 months of age and no later than two years of age.

5. Mumps Vaccine - one dose ~~at 12-15 months of age or by age two years~~ of mumps virus vaccine (live) between 12-15 months of age and no later than two years of age.

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 ~~18 months of age~~ 12 months of age and no later than 18 months of age. For children not receiving three doses between 12-18 months of age, three doses will be required at initial school entry 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 VIII.

CANCER REPORTING

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

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

12 VAC 5-90-180. ~~Data to be Reported~~. Report Contents and Procedures

Each report shall include the patient's name, address (including county or independent city of residence), age, date of birth, sex, date of diagnosis, date of admission or first contact, primary site of cancer, histology (including type, behavior, and grade), basis of diagnosis, social security number, race, ethnicity, marital status, usual occupation, usual industry, sequence number, laterality, stage, treatment, recurrence information (when applicable), name of reporting facility, vital status, cause of death (when applicable), date of last contact, history of tobacco and alcohol use, and history of service in Vietnam and exposure to dioxin-containing compounds.

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

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

Part X.

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TUBERCULOSIS CONTROL

12 VAC 5-90-220. 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; 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 of the treating physician.
    2. A secondary report to be completed simultaneously or within 1-2 weeks following the initial report. The report must include: the date and results of tuberculin skin test (TST); the date and results of the initial and any follow-up chest radiographs; the dates and results of bacteriologic or pathologic testing, the antituberculosis drug regimen, including names of the drugs, dosages and frequencies of administration, and start date; the date and results of drug susceptibility testing; HIV status; contact screening information; and name and address 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 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:
            (i) HIV infection
            (ii) Known or suspected active TB disease resistant to rifampin, rifabutin, rifapentine or other rifamycin with or without resistance to any other drug.
            (iii) A history of prior treated or untreated active TB disease, or a history of relapsed active TB disease.
            (iv) A demonstrated history of non-adherence to any medical

treatment regimen.

B. Laboratories are required to submit the following:
   1. Results of smears which 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*).
   3. Results of rapid methodologies, including acid hybridization or nucleic acid amplification, which are indicative of *M. tuberculosis* complex.
   4. Results of drug susceptibility tests performed on cultures positive for any member of the *M. tuberculosis* complex.
   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.

Part XII.
REPORTING OF DANGEROUS MICROBES AND PATHOGENS

12 VAC 5-90-280. Definitions.

The following words and terms, when used in this regulation, 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 the Code of Federal Regulations, Title 42, Part 73, Section 73.4 ;
2. HHS overlap select agents and toxins, as outlined in the Code of Federal Regulations, Title 42, Part 73, Section 73.5.

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

"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.

"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.

"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 origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, 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 5-90-290. Authority.

Chapter 2 of Title 32.1 of the Code of Virginia authorizes the reporting of dangerous microbes and pathogens to the Department. Specifically, Section 32.1-35 directs the Board to promulgate regulations specifying which dangerous microbes and pathogens are to be reportable and the method and timeframe by which they are to be reported by laboratories.

12 VAC 5-90-300. Administration.

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

12 VAC 5-90-310. Reportable Agents.

The Board declares the select agents and toxins outlined in the Code of Federal Regulations, Title 42, Part 73, Sections 73.4 and 73.5 to be reportable, and adopts it herein by reference including subsequent amendments and editions. The select agents and toxins are to be reportable by the persons enumerated in 12 VAC 5-90-340.

12 VAC 5-90-320. Items to Report.

Each report shall be made on a form determined by the Department and shall contain the following: name, source and characterization information on select agents and toxins and

quantities held; objectives of the work with the agent; location (including building and room) where each select agent or toxin is stored or used; identification information of persons with access to each agent; identification information of the person in charge of each of the agents; and the name, position and identification information of one responsible official as a single point of contact for the organization. The report shall also indicate whether or not the laboratory is registered with the CDC Select Agent Program and may contain additional information as required by the Code of Federal Regulations, Title 42, Part 73 or the Department.

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

Initial reports shall be made within 90 days of the effective date of these regulations. 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 31st 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 select agent or toxin must be submitted to the Department within seven calendar days of submission to the CDC Select Agent Program.

In the event that a select agent or toxin, or a specimen or isolate from a specimen containing a select agent or toxin, has previously been reported to the Department and is subsequently transferred to a facility eligible for receiving the items, a copy of federal forms addressing the transfer of a 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 7 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/in which the release, loss or theft occurred. The report may contain additional information as required by the Code of Federal Regulations, Title 42, 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 5-90-340. Those Required to Report

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

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 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 report. Proper destruction of the agent must take place through auto-claving, 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 the Code of Federal Regulations, Title 42, Part 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.

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 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.