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Final Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90
Regulation title(s)	Regulations for Disease Reporting and Control
Action title	Amendment to comply with changes in public health practice
Date this document prepared	April 1, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and other details related to public health reporting and disease control. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the residents of Virginia.

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health pertaining to the reporting of diseases in humans that are potentially transmitted from environmental sources (e.g., babesiosis and leptospirosis) as well as to update the list of laboratory tests that can be used to identify reportable disease findings and of specimens needing further testing to reflect advances in laboratory technology. Further amendments are

necessary to clarify definitions and ensure consistency of the regulatory language, such as to standardize the reporting requirements for those who are required to report. Minor changes are also proposed to the section on the reporting of dangerous microbes to align the regulatory requirements with federal requirements. Renumbering is proposed for internal consistency and to ensure relevant sections are maintained as a whole.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CDC – Centers for Disease Control and Prevention
DCLS – Division of Consolidated Laboratory Services
FBI – Federal Bureau of Investigation
HIV – Human Immunodeficiency Virus
MERS – Middle East Respiratory Syndrome
SARS – Severe Acute Respiratory Syndrome
VDH – Virginia Department of Health

Statement of final agency action

Please provide a statement of the final action taken by the agency including:1) the date the action was taken;2) the name of the agency taking the action; and 3) the title of the regulation.

The State Board of Health approved the final amendment to the *Regulations for Disease Reporting and Control* on December 3, 2015.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Chapter 2 of Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, § 32.1-42 of the *Code of Virginia* authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The amendment is necessary in order to ensure that the regulations comply with changes in the *Code of Virginia* and recommendations of national public health organizations. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including outbreaks and emergencies that could be caused by naturally occurring disease or acts of bioterrorism. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

- Update definitions to align them with current usage;
- Update the reportable disease list to reflect current national recommendations and language;
- Update the list of conditions reportable by laboratory directors to reflect current laboratory technology and public health standards;
- Increase the information reported by laboratory directors for hepatitis B and human immunodeficiency virus testing and the specimens to be submitted to the Division of Consolidated Laboratory Services or other lab designated by the agency for advanced laboratory testing;
- Update language to ensure consistency between sections;
- Clarify agency role in interstate and national notifications;
- Clarify level of information that may be shared with the agency by schools and other facilities;
- Renumber sections to increase internal consistency within the regulations;
- Update reporting of dangerous microbes and pathogens sections to reflect federal code section numbering changes and other requirements.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The primary advantage to the public is that the Virginia Department of Health will be increasingly aware of conditions of public health concern so that staff can take action to reduce the risk of preventable acute diseases. No disadvantages to the public are known.

The primary advantage to the agency is that the proposed amendments will improve the ability of the Virginia Department of Health to detect and control diseases of public health importance. Most of the changes being proposed are updates to terminology to reflect current usage or to clarify requirements. Some formatting changes have also been proposed.

The impact on businesses primarily affects laboratories conducting business in the Commonwealth. The addition of laboratory testing methods to the list of conditions that laboratory directors must report reflects advances in laboratory science, but would mean that laboratories conducting business in Virginia will have to report additional positive laboratory findings to the health department. Many of the proposed changes are already being reported by laboratories who offer those testing options.

The amendments would require laboratory directors to provide additional information on hepatitis test results and antimicrobial susceptibility for gonorrhea. Amendments also require lab directors to submit remnant sera from HIV positive diagnostic tests to DCLS or another approved laboratory for HIV recency testing and provide electronic genetic sequence data from HIV drug resistance tests. They would also report all HIV test results for children under 3 years of age. Another noteworthy change is that the reportable blood lead level is proposed to be any detectable level for children and $\geq$ 5 µg/dL for persons 15 years of age or older.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

None of these requirements is more restrictive than federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

The impact of these changes is anticipated to be similar for all localities.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-90-10	Arboviral infection definition referred to chikungunya but did not define an acronym and did not mention Zika virus; 'Acute care hospital', 'adult intensive care unit', 'central-line associated bloodstream infection', and 'central line device' were defined but not used in the subsequent text; Definitions for 'companion animal', 'essential needs', and 'school' were not consistent with Code; 'Coronavirus infection, severe' was captured under SARS; Definition of 'department' referred to the 'State Department of Health'; Throughout 'health care' was proposed as a change from 'healthcare'; Definition for hepatitis C referred to signal-to-cutoff ratio and RIBA test and 400 as the criteria for liver enzyme levels; Definition of elevated blood lead levels was set at CDC reference levels and the latest (2012) reference levels were provided.	Acronym 'CHIK' was added for the arbovirus, chikungunya, and Zika virus was added as another example of an arbovirus; Definitions for the four terms that were not used later were deleted; Definitions were edited to ensure consistency with the *Code of Virginia*; Separate definition was added for 'Coronavirus infection, severe' and the definition for SARS was deleted; Definition of 'department' was expanded to include the 'Virginia Department of Health' and to introduce the acronym 'VDH'; Changed back to the original use of 'healthcare'; Definition for hepatitis C was updated to delete reference to signal-to-cutoff ratio and RIBA test and to lower the criteria for liver enzyme levels to 200; Definition of reportable blood lead levels was updated to refer to any detectable level in children (15 years of age and younger) and $\geq$ 5 µg/dL in those over the age of 15 years.	Defined the acronym for chikungunya and added Zika so they could be used in 12VAC5-90-80; It was unnecessary to define terms that were not used; Discrepancies between Code and Regulations on these terms were eliminated; Combining the definitions for SARS and MERS under the definition of SARS was confusing, putting them both under coronavirus helps make the definition clearer; Defining VDH allows the acronym to be used later in the document; 'Healthcare' is the phrase used most often; Laboratory techniques and surveillance definitions for hepatitis C have changed and the new language reflects current usage; Defining specific reportable levels will be clearer for laboratories rather than incorporating a reference that is expected to change over time.
12VAC5-90-80	The requirement to report arboviral diseases did not specify that it included CHIK or Zika; SARS was a reportable disease and the intent to use that heading to also capture MERS and other serious coronavirus	Added reference to 'CHIK' and Zika under arboviral diseases; Added 'coronavirus infection, severe' to reportable disease list and deleted SARS in Sections A, B, and C; For campylobacteriosis added required reporting of culture results from nucleic acid detection	Chikungunya and Zika virus infections are important emerging arboviral diseases and the Agency wanted to ensure those who report diseases knew they were reportable; Combining SARS and

Section number	Requirement at proposed stage	What has changed	Rationale for change
	infections was included in 12VAC5-90-10; For campylobacteriosis, the Agency proposed to require laboratories to report culture results from antigen detection tests; 'Lead, elevated blood levels' was the term used for this reportable condition; The Agency proposed to require reporting of outbreaks of 'health care-associated infections'; Laboratory methodologies listed for the following diseases were not inclusive of current technology: anthrax, babesiosis, cholera, ehrlichiosis/anaplasmosis, E. coli, Shiga toxin-producing, gonorrhea, hepatitis B, hepatitis C, HIV, lead, listeriosis, meningococcal disease, pertussis, Q fever, salmonellosis, shigellosis, streptococcal disease, syphilis, typhoid/ paratyphoid fever, and Vibrio infection. No examples were provided of which diseases constitute an arboviral infection.	tests; 'Lead, reportable levels' is the new term being used in this regulation for this reportable condition; The Agency requires reporting of outbreaks of 'healthcare-associated infections'; Updated the reportable laboratory methodologies for all the diseases listed in the column to the left and added examples of arboviral infections.	MERS under a new category referred to as coronavirus will clarify the reporting requirement; For campylobacteriosis, the accuracy of antigen detection and nucleic acid detection tests is unknown and more information is needed about culture confirmation for both tests; 'Healthcare' is the proper term to use in this instance; The definition of reportable blood lead levels required the change in nomenclature; Laboratory methodologies for infectious diseases are rapidly evolving and public health inserted edits to reflect the latest laboratory tests in use to confirm the diagnosis of reportable conditions. Adding examples of arboviral infections can help laboratories know which results must be reported to the health department.
12VAC5-90-90	No mention was made of directors of laboratories needing to report genetic nucleotide sequence data associated with HIV drug resistance tests electronically or to forward remnant sera from HIV positive diagnostic tests to DCLS, the state laboratory, or other approved laboratory; Reporting on Epi-1 forms or CDC surveillance forms was allowed; Mentioned reporting by the most rapid means	The requirements related to HIV surveillance were added; Permission to also report using a VDH surveillance form was added; Specific language was inserted throughout to identify telephone reporting as the preferred method for immediate reporting; Botulism and tularemia were added to the list of specimens labs have to send to the state lab; Added available lab tests and results to information to be reported by physicians; Edited content to refer to 'laboratory directors' in place of extraneous words that were	Genetic sequence data are reported in large files that do not lend themselves to keying into a database; Further testing of positive HIV sera at a designated recency lab will aid in HIV surveillance locally and nationwide as it provides a more accurate picture of the spread of new HIV infections and helps to more clearly identify groups who are contracting HIV and where prevention efforts

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	available; Botulism and tularemia were not included in the list of specimens that lab directors have to submit to the state lab; Lab data were not included in the required contents of physician reports; Some unclear, inaccurate, or excessive terminology was included.	already included in the definition, to clarify that physicians request the lab tests, to correct a typographical error in the sentence about reporting to CDC, and to make a change in one place that had been missed before (to change 'applicants' to 'conditional employees' in section G).	should be focused; Specialized testing available at the state lab is necessary to confirm these organisms; Public health will be able to take action more quickly if confirmatory laboratory data are included in initial disease reports; Edits clarify and correct language included in the proposed text.
12VAC5-90-110	Language was included that stated that immunizations could be given by licensed professionals in private settings or local health departments.	The reference to setting locations was deleted.	The language was not necessary.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Infection Preventionist, Central Region	Town Hall – Add Middle East Respiratory Syndrome (MERS) to Severe Acute Respiratory Syndrome (SARS) for clarification.	Under Definitions and sections A, B, and C of 12VAC5-90-80, deleted SARS and added 'coronavirus infection, severe', noting that it pertains to SARS and MERS
District Health Director, Central Region	Town Hall – 1) Recommend not lowering the reportable blood lead level unless that level causes harm and actions can reduce the lead in the blood; 2) Recommend requiring laboratories to report to the health department of the patient's residence or the ordering physician or facility rather than where the lab is located or establish one number in the central office where disease reports can come in and be dispatched to the proper locality.	Regarding item 1), lowering the reportable blood lead level will aid in identifying children exposed to lead and help eliminate the problem of lead in the environment. No safe blood lead level exists. Regarding item 2), allowing facilities to send all disease reports to the local health department where they are located minimizes the reporting burden and aids in compliance. No changes are necessary. The Agency will consider the feasibility of establishing a disease report call line in the future.

Commenter	Comment	Agency response
VDH Epidemiologist, Central Office Foodborne Program	Email – Could labs be asked to report tests that are positive 'by any method' rather than specifying the methods?	The Agency will consider the feasibility and possible impact of making this change in the future.
VDH District Epidemiologist, Southwest Region	Email – Requested interpretation of proposed requirement for labs to report all hepatitis B findings in children under 2 years of age and all HIV results in children under 4 years of age.	Only positive results for hepatitis B in children are needed. As they are already required, this proposed change was deleted. The requirement for all HIV results in children <3 was reworded to be clearer in the final text.
VDH Epidemiologist, HIV Program	Email - Recommended changes in the laboratory reporting requirements for HIV infection clarifying that undetectable viral loads are included and added language in 12VAC5-90-80.B and 12VAC5-90-90 to state that genetic sequence data on HIV drug resistance must be submitted electronically.	These changes have been incorporated into the final text.
Infection Preventionist, SW Region	Email – Supportive of proposed changes.	No change necessary
Private Lab Director, SW Region	Email – 1) Requested clarification on the age for children for whom all HIV test results would be reported; 2) reported that labs cannot report liver function test results; and 3) asked if IgG above the reference range with a negative IgM for West Nile virus should be reported.	Regarding item 1), the Agency HIV surveillance program clarified that age <3 is intended and that is reflected in the final text. Regarding item 2), the regulations state that those results should be submitted by labs if available. Regarding item 3), labs must report serologic evidence of recent infection, so while reports of both IgM and IgG are helpful from a clinical perspective, IgG results are not required to be reported to VDH. Labs may continue to voluntarily submit IgG results along with any IgM results for WNV.
Plasma Services Center, Central Region	Letter – Stated that it would create a staff and financial burden to submit HIV positive samples to the state lab (DCLS) and they would need technical information before they could ship.	Plasma centers and blood donation centers performing only donor screening tests are not subject to submitting HIV diagnostic remnant sera to DCLS or a lab designated by VDH for recency testing. That requirement pertains only to confirmatory diagnostic tests and not to screening tests.
Major Health System, Central Region	Letter – 1) To report all the hepatitis and HIV results in children would require 6 months of work by the IT team; 2) submitting HIV remnant sera to DCLS would have significant staffing implications, with labor and shipping costs; 3) shipment of influenza specimens is equally burdensome; 4) clarify request for coronavirus is for more serious strains such as MERS or	Regarding item 1), the Agency understands implementation challenges and will be supportive of reporting as institutions transition to new methods of reporting. The requirement for reporting all hepatitis results in young children was deleted in the final text. Regarding item 2), the importance of improving the understanding of HIV infection and detecting recency of infection are significant. HIV Incidence Surveillance (HIS) is conducted in only 25 jurisdictions, including Virginia; HIS

Commenter	Comment	Agency response
	SARS; 5) add smear evaluation to the test methodologies for Babesia; 6) clarify responsibility for reporting results generated by outside reference labs (they come as large text records).	estimates provide a more accurate picture of the spread of new HIV infections and help to more clearly identify groups who are contracting HIV and where prevention efforts should be focused. Securing remnant diagnostic sera from laboratories confirming positive HIV tests is crucial for the estimation process. Laboratories currently submit sera voluntarily and Virginia has struggled to attain the required benchmark that is needed so as to get estimates that are stable and reliable. Other jurisdictions have found that having regulations that require remnant sera to be submitted for recency testing improves the success of the program. The Agency will discuss logistical options with facilities. Regarding item 3), only novel influenza viruses have to be forwarded to DCLS, and those should not occur unless a pandemic may be beginning, in which case further identification of the virus is necessary. Regarding item 4), this issue has been addressed in the final text as stated above. Regarding item 5), this addition was made in the final text. Regarding item 6), laboratories in Virginia need to report the results of tests they run in house or those run by an out-of-state reference lab. They do not have to report results generated by in-state reference labs, which fall under the reporting requirements of the Board of Health.
VDH Epidemiologist, Central Office Surveillance Program	Email - What blood lead levels should laboratories report?	The final amendment reflects the requirement for laboratories to report all detectable blood lead levels in children age 0-15 years and $\geq$ 5 µg/dL in those >15 years of age
VDH State Epidemiologist	Email – 1) expressed concern about noting the current (2012) blood lead levels and suggested creating an annual companion document for labs with reference levels in case the levels change; 2) requested consensus on the MERS/SARS language; 3) suggested changes in 12VAC5-90-110 related to wording about licensed professionals who can administer immunizations and where.	Regarding item 1), the confusion about reportable blood lead levels has been resolved in a way that referring to a separate document will not be necessary. Regarding item 2), this issue has been addressed in the final text. Regarding item 3), this change was incorporated into the final text.
District Health Director, Northern Region	Email - Suggested changing the rapid reporting language from 'immediately by the most rapid means available' to 'immediately by telephone to the local health department emergency contact'	The requirement to report by the most rapid means available specifies that telephone reporting is preferable. The preference for telephone reporting was added each time mention was made of immediate reporting.

Commenter	Comment	Agency response
VDH Division Director, Central Office, Disease Prevention	Email - Suggested changes to the lab reporting requirements for syphilis and gonorrhea	These changes have been incorporated into the final text
Infectious disease physician, NW Region	Email – Sought clarification as to whether VDH wants all HIV viral loads, CD4 counts, and resistance test results on all patients for the rest of their lives.	That is the Agency's intent in order to allow monitoring of treatment effectiveness. No change is necessary.
VDH Perinatal Hepatitis B Coordinator	Email – Stated that the program does not need negative lab results on children under 2 years of age for hepatitis B	This requirement was deleted from the final text.
VDH Division Director, Environmental Epidemiology	Email - Recommended a change to wording in the reportable level for elevated blood lead levels, removing the reference to the current CDC level and instead suggesting that reference documents be incorporated by reference into the regulation.	The requirement was changed to all detectable blood lead levels being reportable in children and levels ≥ 5 in persons over 15 years of age, thereby simplifying and clarifying the requirement and eliminating the need for guidance documents for laboratories.
Director, Division of Consolidated Laboratory Services	Email – 1) Suggested many updates related to laboratory test methods in 12VAC5-90-80.B, conditions reportable by laboratory directors. 2) Recommended deleting reference to the RIBA test for hepatitis C in the Definitions section and the Lab reporting section. 3) Recommended against combining MERS with SARS.	Regarding item 1), all proposed changes were reviewed carefully and compared with national case definitions. Changes were made throughout the list to ensure it reflected current and anticipated laboratory methods. Regarding item 2), reference to the RIBA test was deleted in both places. Regarding item 3), the coronavirus item has been addressed.
VDH Epidemiologist, Central Office, Foodborne Program	Email – 1) Stated that retaining the different genuses under vibriosis was important and suggested that we refer to the Family Vibrionaceae (other than toxigenic V cholera O1 or O139); 2) suggested requiring the reporting of culture-independent diagnostic tests for enteric pathogens and coordinating with DCLS to determine which specimens should be forwarded to the state lab if they test positive by a non-culture lab method.	Regarding item 1), the suggested wording has been incorporated into final text. Regarding item 2), the use of antigen detection and nucleic acid detection tests have been added to lab reporting requirements for enteric pathogens. The discussion of a requirement for laboratories to forward specimens to DCLS for additional conditions must be deferred until a future regulatory amendment so that laboratory directors will have an opportunity to comment on proposed changes.
VDH Epidemiologist, Central Office, Reportable Disease Surveillance	Email – Reviewed the laboratory reporting requirements compared to national case definitions and recommended changes throughout to ensure consistency between the documents.	All proposed changes were reviewed carefully and compared with national case definitions and the recommendations of DCLS. Changes were made throughout the list to ensure it reflected current and anticipated laboratory methods.

Commenter	Comment	Agency response
VDH Epidemiologist, Central Office Manager	Email – Recommended that VDH consider whether the definition of laboratory needs to be changed to clearly include blood collection centers and plasma centers.	The Agency verified that the definition of laboratory did not need to be amended.
VDH Epidemiologist, Central Office, Immunizations	Email – Encouraged the addition of serologic tests to reportable laboratory tests for pertussis; recommended changes to 12VAC5-90-110 clarifying professionals that can give immunizations.	Both of these recommendations are reflected in the final text.
VDH District Health Director, Central Region	Email - Asked for clarification as to whether school nurses can give immunizations under 12VAC5-90-110.	Agency verified that the *Code of Virginia* specifies that school nurses are not allowed to administer vaccines to minors unless a prescriber is on-site. No change in the regulatory language is necessary.
VDH Director of Public Health Nursing	Email - Asked who will provide updated guidelines for follow up testing and evaluation of children with elevated blood lead levels.	The VDH Division of Environmental Epidemiology and VDH Office of Environmental Health Lead Safe Program can assist with this effort.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Multiple		Multiple	All changes listed in the table above under the heading 'Changes made since the proposed stage'.
12VAC5-90-10		Definitions	• Defines Centers for Disease Control and Prevention (CDC) and changes its usage upon later referral. • Changes capitalization on 'Ehrlichiosis/Anaplasmosis' for consistency.
12VAC5-90-50	Repeal	Applicability Section	• This section stated that the regulations apply throughout the Commonwealth and are governed by the Administrative Process Act. Legislative Services advised that it is not necessary and is redundant with Code requirements.
12VAC5-90-80.A		Reportable disease list	• Additions to the reportable disease list include babesiosis and leptospirosis. • Deletes monkeypox from the reportable disease list. The Department has other

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			means of receiving data on the occurrence of this disease.
12VAC5-90-80.B		Conditions reportable by directors of laboratories	• Additions include babesiosis, hepatitis-other acute viral, and leptospirosis. • Deletions include monkeypox and methicillin-resistant *Staphylococcus aureus* infections. • Changes are proposed to the reportable results for botulism, Campylobacter infection, *E. coli* infection, giardiasis, gonorrhea, hepatitis B, hepatitis C, HIV, lead, salmonellosis, shigellosis, Staphylococcal infection, and Vibrio infection to incorporate current laboratory methods. • Laboratories would report all HIV results for children under 3 years of age. • Laboratories would submit all remnant HIV sera to the Division of Consolidated Laboratory Services (DCLS) or other designated laboratory for HIV recency testing and would report all HIV genetic sequence data associated with HIV drug resistance testing.
12VAC5-90-80.C-F		Rapidly reportable conditions, toxic substances, outbreaks, and unusual diseases	• Deletes monkeypox. • Clarifies that rapid reporting means immediately by the most rapid means, using consistent language between sections.
12VAC5-90-90		Those required to report	• Changes are proposed in wording for consistency between all the subsections, including clarification of rapid reporting. • The term 'broth' is clarified and Vibrio is added to the list of isolates that must be submitted to the Division of Consolidated Laboratory Services (DCLS) for further testing. • Laboratories suspecting a diagnosis of a select agent would submit an isolate to DCLS for confirmation. • Clarifications are added that local health departments can report to the state using the electronic surveillance system and that the state is responsible for notifying other states and the Centers for Disease Control and Prevention. • Clarification of what information may be released to the health department by schools, camps, and facilities on individuals has also been added.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-90-100		Methods of disease control	• Proposes to update language to refer to the 20th edition (2015) of the *Control of Communicable Diseases Manual*.
12VAC5-90-110		Immunization	• States that required immunizations may be obtained from physicians, registered nurses, or other licensed professionals as authorized by the *Code of Virginia*.
12VAC5-90-280 through 12VAC5-90-360		Reporting of dangerous microbes and pathogens	• Strikes section numbers and changes them to letters for consistency within the regulations; • Proposes to update references to the *Code of Federal Regulations* to reflect changes in federal code section changes for select agent reporting; • Proposes to add language to clarify that select agent information is protected from release regardless of whether the information is submitted directly by laboratories or by federal agencies also holding the information. This is needed to ensure that terrorism-sensitive information is protected from access by potential terrorists seeking access to the materials.