



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-90
Regulation title	Disease Reporting and Control
Action title	Update of Regulations and Adoption of New (Emergency) Regulations for Quarantine and Isolation
Document preparation date	December 17, 2004

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

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 how reporting is conducted. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the *Code of Virginia* and with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the citizens of Virginia.

The proposed amendment makes final the emergency regulations addressing isolation and quarantine. In addition, the amendment includes the addition and clarification of several definitions, clarifications on the reportable disease list, updates to the list of conditions reportable by laboratories and the tests used to confirm those conditions, revisions to the information submitted on a disease report, and updates to tuberculosis reporting and control requirements.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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*. The Office of the Attorney General has certified that the agency has statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The proposed amendment to the *Regulations for Disease Reporting and Control* will replace emergency regulations for isolation and quarantine with final regulations. Additional changes are proposed to the existing disease reporting and control regulations to ensure that they comply with current public health practices, medical guidelines and scientific terminology. This will facilitate efforts to recognize, measure and contain emerging diseases in order to protect the health of the people of the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Amendments to current regulations will:

- Finalize the emergency regulations on isolation and quarantine requirements;
- Update language to ensure that it reflects current public health, medical and scientific terminology;
- Update disease reporting requirements, including reportable diseases and those required to report;
- Update language regarding laboratory reporting requirements;
- Update tuberculosis reporting and control requirements and definitions;
- Update provisions regarding the reporting of toxic substance-related illness;

- Update requirements related to HIV testing and reporting, including the reporting of viral load and CD4 test results; and
- Update other disease reporting and control provisions necessary to protect the health of the people of the Commonwealth.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

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 some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Except as noted in the paragraphs below, changes are alterations in language and terminology to reflect current scientific use and to provide clarification. For example, the list of diseases reportable by laboratory directors is updated to reflect the currently available tests for these diseases and names of conditions on the Reportable Disease List are modified to comply with scientific usage. These changes in language improve the clarity of the regulations but are not substantive.

Finalization of emergency regulations on isolation and quarantine: These regulations are required by Articles 3.01 and 3.02 of Chapter 2 of Title 32.1 of the *Code of Virginia*. Failure to finalize these emergency regulations would leave the agency and the Commonwealth without the required regulations to support the *Code of Virginia* and would limit our ability to respond effectively in a biological attack or severe disease outbreak in which isolation and/or quarantine may be necessary.

Update to disease reporting requirements: Influenza deaths in children <18 years of age is added to the list of conditions that must be reported. Influenza deaths in children occur, but are unusual and may be indicative of a severe strain circulating in the population. To better monitor trends in severe influenza, VDH has requested voluntary reports of pediatric deaths during the last two years under §32.1-36.E. of the *Code of Virginia*. With this change, reporting of these severe influenza events would be required. Less than five reports are anticipated annually, unless an unusual strain of influenza emerges. Yersiniosis is added to the list of conditions which must be reported. This foodborne disease causes severe illness, especially in infants. Less than 15 reports of yersiniosis are anticipated annually. Typhoid fever, a condition for which public health notification is currently required, is incorporated into the list of conditions requiring rapid communication. This will enable rapid identification and response. Information on pregnancy status for females and contact information for the physician and facility are needed for follow-up and investigation of reported disease cases. Pregnancy status is currently reportable only for hepatitis B cases, but the information is needed in other reportable conditions where health department action can help prevent infection in the infant. Pregnancy status will receive the same legal protection as other confidential diagnostic information collected on the disease report. No additional tests or data collection related to pregnancy status are being requested. The agency is requesting only that this information be reported if it is available. Inclusion of physician/facility contact information on the disease report will facilitate follow-up and investigation of reported disease cases. These changes present no disadvantages to the public, the agency, or the Commonwealth.

Update to language regarding laboratory reporting requirements and update of provisions regarding reporting of toxic substance-related illness: Laboratory test names are updated to reflect current laboratory methodologies. Four conditions are added to the list of conditions reportable by laboratory directors. Hantavirus pulmonary syndrome is currently included on the list of reportable conditions and is being added to the list of conditions to be reported by laboratory directors to ensure the reporting of positive laboratory findings. Because hantavirus infection is rare (only two Virginia cases have occurred, in 1993 and 2004) the volume of reports will be low. Toxic substance-related illness is required to be reported by laboratory directors in another section and is being added to this list for clarity. Typhoid fever is currently reportable as a *Salmonella* infection. A change in terminology requires that typhoid fever be listed separately. Yersiniosis is added to support detection of this severe foodborne illness. Less than 15 reports of yersiniosis are anticipated annually. Laboratory reporting of these conditions complements physician reporting and is needed for early detection of and appropriate response to cases. There should be no adverse effect on laboratories as a result of these changes.

Update of the tuberculosis reporting requirements: A revision in the wording of the requirement for reporting of susceptibility results for cultures positive for any member of the *M. tuberculosis* complex makes the regulatory language consistent with the language in the *Code of Virginia*. It improves consistency and clarifies requirements but presents no change in requirements.

Update of requirements related to HIV testing and reporting, including reporting of CD4 and HIV viral load test results: The Centers for Disease Control and Prevention (CDC) support state-mandated reporting of all viral load and CD4 test results for HIV-infected individuals. Adding this requirement will help Virginia compete for federal funds for HIV surveillance, prevention and care. Currently, of the 54 states and territories within the U.S. HIV/AIDS Surveillance system, 26 require both CD4 and viral load reporting. At least 12 additional states are actively working to amend their state reporting regulations to include reporting of these test results. Reporting of all viral load and CD4 tests will improve HIV reporting timeliness and efficiency. In addition, this reporting will allow Virginia to accurately measure care services and ultimately justify federal funding for those Virginians living with HIV infection. Strict confidentiality provisions will continue to be enforced to protect this information when it is received by VDH. This requirement will expand the volume of reports submitted by laboratories to VDH. However, because most laboratories already use computerized systems that generate automated printouts of the required information or submit reports using encrypted data files, the burden of generating additional reports will be minimized.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</p>	<p>The only foreseeable cost to the state will be in managing the larger volume of HIV-related reports due to the implementation of CD4 and HIV viral load reporting. Virginia Department of Health's HIV/AIDS Surveillance team in the central office will assume this burden of work. They are supported exclusively with federal funds. Efficiencies provided by a new data system scheduled for implementation in 2005 will partially offset the additional effort required for processing reports.</p>
<p>Projected cost of the regulation on localities</p>	<p>There should be no economic impact on localities. Local health departments and health districts will act only as a pass-through for the additional HIV reports.</p>

Description of the individuals, businesses or other entities likely to be affected by the regulation	The volume of reports submitted by laboratories will increase due to the change in HIV-related reporting. However, most laboratories already use computerized systems that generate automated printouts of the required information or encrypted data files.
Agency's best estimate of the number of such entities that will be affected	It is estimated that a maximum of 140 laboratories may be affected.
Projected cost of the regulation for affected individuals, businesses, or other entities	Laboratories may encounter minimal additional postage costs due to the increased volume of reports submitted on HIV-infected individuals.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives have been considered, nor are there any advisable.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
	No comments were received during the public comment period following publication of the NOIRA.	

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

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.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-90-10		Definitions	<ul style="list-style-type: none"> • Replace existing language with changes to definitions made by emergency regulation on November 5, 2004. • Affected Area – Change since filing of emergency regulation to move phrase within the sentence and modify punctuation to clarify wording. • Decontamination – Change since filing of emergency regulation to re-order “surface, item or person” to read “person, surface, or item”. • Hepatitis C – Reword to reflect current testing methodology. • Infection – Change since filing of emergency regulation to read: “Infection” means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent). • Nucleic acid detection – Add a definition to clarify use of this term in diseases reportable by directors of laboratories. • Occupational outbreak – Add pneumoconiosis as a disease indicative of an occupational health problem. • Susceptible individual – Change since filing of emergency regulation to modify “immunization exposure, or medications” to “immunization history, or use of medications.” • Tuberculosis – Re-order definitions to alphabetize. Reword definition of tuberculin skin test to be consistent with current medical guidelines. • Vaccinia, disease or adverse event – Add phrase to ensure that vaccinia

			<p>infection is included.</p> <ul style="list-style-type: none"> • Vancomycin-resistant <i>Staphylococcus aureus</i> – Delete defined term. Clarifications in the Reportable Disease List make this definition unnecessary.
12 VAC 5-90-40		Administration	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Change since filing of emergency regulation to insert the word “has” in paragraph B to improve clarity. The phrase will read “...and has the authority to issue orders of isolation...”
12 VAC 5-90-80 (A)		Reportable disease list	<ul style="list-style-type: none"> • Change disease names to comply with scientific usage and ensure internal consistency. • Add influenza deaths in children <18 years of age as a reportable condition and as a condition for which rapid communication of a suspected or confirmed case is required. • Add typhoid fever to the list of conditions for which rapid communication of a suspected or confirmed case is required. • Add yersiniosis as a reportable condition. • Delete typhus as a reportable condition.
12 VAC 5-90-80 (B)		Diseases reportable by directors of laboratories	<ul style="list-style-type: none"> • Add statement to clarify that an asterisk indicates a condition requiring rapid communication. • Update test names to reflect current methodology and terminology. • Add hantavirus pulmonary syndrome, typhoid fever and yersiniosis to the diseases reportable by laboratory directors. • Include toxic substance-related illness and typhoid fever in the list of diseases reportable by directors of laboratories to clarify the reporting of these conditions. • Add CD4 and HIV viral load tests as findings to be reported for persons infected with HIV. • Delete typhus as a reportable condition.
12 VAC 5-90-80 (C)		Reportable diseases requiring rapid communication	<ul style="list-style-type: none"> • Add influenza deaths in children <18 years of age as reportable condition and as condition for which rapid communication of a suspected or confirmed case is required. • Add typhoid fever to the list of conditions for which rapid communication of a suspected or confirmed case is required.
12 VAC 5-90-80 (E)		Human immunodeficiency virus (HIV) infection	<ul style="list-style-type: none"> • Delete sub-section. The information is effectively captured in subsections A and B.

12 VAC 5-90-80 (F)	12 VAC 5-90-80 (E)	Toxic substances-related disease	<ul style="list-style-type: none"> • Renumber to reflect deletion of subsection on HIV infection.
12 VAC 5-90-80 (G)	12 VAC 5-90-80 (F)	Outbreaks	<ul style="list-style-type: none"> • Renumber to reflect deletion of subsection on HIV infection.
12 VAC 5-90-80 (H)	12 VAC 5-90-80 (G)	Unusual or ill-defined diseases or emerging pathogens	<ul style="list-style-type: none"> • Renumber to reflect deletion of subsection on HIV infection.
12 VAC 5-90-90		Those Required to Report	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Add pregnancy status for females and contact information for physicians/facilities as information to be reported. • Clarify that when a facility director submits disease notifications for laboratories, the laboratories are still responsible for submission of required isolates.
12 VAC 5-90-100		Methods	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Change since filing of emergency regulation to clarify wording in first sentence of fifth paragraph regarding the decision to implement modified isolation. • Change since filing of emergency regulation to replace “any individual(s)” with “any individual or individuals” in second sentence of fifth paragraph. • Change since filing of emergency regulation to move last sentence of sixth paragraph to create a seventh paragraph discussing use of articles 3.01 for disease control and 3.02 for isolation and quarantine. Insertion of “of the <i>Code of Virginia</i>” following reference to Article 3.01. • Change since filing of emergency regulation to insert references to sections within the Code of Virginia to accompany citations of articles.
12 VAC 5-90-105 in emergency regulations	12 VAC 5-90-103	Isolation for Communicable Disease of Public Health Threat	<ul style="list-style-type: none"> • Implement additions made by emergency regulation on November 5, 2004. • Correct numbering of section to 12 VAC 5-90-103. Section was incorrectly numbered 12 VAC 5-90-105 in emergency regulations. • Change since filing of emergency regulation to ensure consistent capitalization in subsection titles. • Change since filing of emergency regulation to replace “the individual(s) and or affected area” with “the individual,

			<p>individuals, and/or affected area” in the first sentence of subsection B.</p> <ul style="list-style-type: none"> • Change since filing of emergency regulation to replace “others” with “other individuals” in the second sentence of subsection C. • Change since filing of emergency regulation to replace “individual or individuals affected” with “affected individual or individuals” in first sentence of subsection D. • Change since filing of emergency regulation to replace “would” with “shall” in second sentence of subsection D. • Change since filing of emergency regulation to insert new subsection H (Appeals) to address appeal of isolation orders. • Change since filing of emergency regulation to renumber old subsection H (Release from Isolation) as subsection I. • Change since filing of emergency regulation to renumber old subsection I (Affected Area) as subsection J and to clarify wording in last sentence of subsection J to ensure consistency in the designation of the affected area.
<p>12 VAC 5-90-110 in emergency regulations</p>	<p>12 VAC 5-90-107</p>	<p>Quarantine</p>	<ul style="list-style-type: none"> • Implement additions made by emergency regulation on November 5, 2004. • Correct numbering of section to 12 VAC 5-90-107. Section was incorrectly numbered 12 VAC 5-90-110 in emergency regulations. • Change since filing of emergency regulation to ensure consistent capitalization in subsection titles. • Change since filing of emergency regulation to replace “the individual(s) and or affected area” with “the individual, individuals, and/or affected area” in the first sentence of subsection B. • Change since filing of emergency regulation to clarify wording regarding place of quarantine in second paragraph of subsection C. • Change since filing of emergency regulation to replace “individual or individuals affected” with “affected individual or individuals” in first sentence of subsection D. • Change since filing of emergency regulation to replace “would” with “shall” in second sentence of subsection D. • Change since filing of emergency

			<p>regulation to insert new subsection H (Appeals) to address appeals of quarantine orders.</p> <ul style="list-style-type: none"> • Change since filing of emergency regulation to renumber old subsection H (Release from Quarantine) as subsection I. • Change since filing of emergency regulation to renumber old subsection I (Affected Area) as subsection J and to clarify wording in last sentence of this subsection to ensure consistency in the designation of the affected area.
12 VAC 5-90-110 (12 VAC-90-120 in emergency regulations)	12 VAC-90-110	Dosage and Age Requirements for Immunizations: Obtaining Immunizations	<ul style="list-style-type: none"> • Correct numbering of section to 12 VAC 5-90-110. Section was incorrectly numbered 12 VAC 5-90-120 in emergency regulation. • Change wording of vaccine requirements for consistency and clarity, using the phrase “attenuated (live virus)” where appropriate. • Clarify wording of age and school entry requirements for hepatitis B vaccination.
12 VAC 5-90-130		Prenatal Testing	<ul style="list-style-type: none"> • Insert wording on HIV prenatal testing for consistency with <i>Code of Virginia</i> § 54.1-2403.01.
12 VAC 5-90-225		Additional Data to be Reported Related to Persons with Active Tuberculosis Disease (Confirmed or Suspected)	<ul style="list-style-type: none"> • Modify the requirement for laboratory reporting of drug susceptibility testing to be consistent with current requirements in the <i>Code of Virginia</i>. • Require reporting of health care provider’s telephone number to facilitate follow-up. • Clarify the organisms for which cultures must be submitted.
12 VAC 5-90-230		Definitions	<ul style="list-style-type: none"> • Re-order definitions to alphabetize.
12 VAC 5-90-280		Definitions	<ul style="list-style-type: none"> • Clarify the reference for the definition of “select agent or toxin”. • Move definitions to place in alphabetical order.

Enter any other statement here