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Final Regulation
Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-90 and 12VAC5-120
Regulation title(s)	Regulations for Disease Reporting and Control and Regulations for Testing Children for Elevated Blood Lead Levels
Action title	Updating Disease Reporting Regulations and Repealing Lead Testing Regulation
Date this document prepared	November 6, 2015

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 amending the regulations to bring them into compliance with recent changes in the field of environmental disease control that are needed to protect the health of the citizens of Virginia.

Specifically, the agency is incorporating the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and repealing 12VAC5-120, the existing regulation pertaining to blood lead testing of children.

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.

No acronyms are used without being defined in context.

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. §32.1-46.1 authorizes the Board to establish a protocol for the identification of children with elevated blood lead levels. 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. 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 proposed amendment will improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for detectable blood lead levels in children. The changes will position the agency to better detect and respond to these environmental exposures 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.

The section on testing children to determine their blood lead levels is new to the *Regulations for Disease Reporting and Control* but reflects minor amendments to existing requirements that are currently included in another set of agency regulations, 12VAC5-120. The agency decided it was a logical and efficient change to incorporate the lead testing requirements into the set of regulations that addresses the reporting of elevated blood lead levels. Having one set of regulations on this topic should reduce confusion among the regulated community.

12VAC5-120, the existing regulation pertaining to the identification of children with elevated blood lead levels is being repealed as its content is being incorporated into 12VAC5-90. Some changes are also being made to simplify and clarify the requirements, remove unnecessary references to guidelines and non-mandatory actions, and reflect current Centers for Disease Control and Prevention recommendations. The proposed amendment to 12VAC5-90 pertaining to blood lead levels in children reflects a similar schedule of testing, risk factors for testing, criteria for determining low risk, and need for confirmatory testing as is currently provided in 12VAC5-120.

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 advantages to the public will be clearer rules for testing children for exposure to lead and less confusion that is inherent in maintaining two sets of regulations pertaining to the same subject and procedures.

The primary advantages to the agency are the same as for the public. That is, elimination of the confusion caused by needing to track multiple sets of regulations or the potential for inconsistent requirements in different regulations.

No disadvantages or other pertinent matters of interest to the regulated community have been identified.

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
		No changes	

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
Public Health Nurse, Chesterfield Health District	Capillary lead levels 5-9 being repeated by preferred venous stick 1 – 3 mos. is new. No health department involvement until 10 – 44 with follow up 1 week – 1 month	No changes needed. Comment summarizes the new features of the requirement and is generally supportive of the change.

Commenter	Comment	Agency response
	and case management. CDC will update the reference value every 4 years. I think this is clear and it's nice it is in one statute. Goes along with the fact sheet that we were given when the CDC lowered the level. I notice it is not "lead poisoning" or "level of concern" but "exposure to lead" below 10. Above 10 is "level requiring case management".	
United Parents Against Lead (UPAL)	Combining the two regulations into one will be less confusing, but the wording does nothing to ensure that children, even those deemed at-risk, will be tested for elevated blood lead levels. A major concern is that there is no uniform lead level of concern in Virginia. The action level varies from locality to locality (e.g.,Henrico's is 20 ug/dL while Richmond/Chesterfield is 15 ug/dL). We should include wording in the regulations that would make the action level uniform across the state. Otherwise the testing and screening process that leads to case management and prompts residential lead inspections/risk assessments is convoluted and designed for failure to the detriment of our children. The Commonwealth's level should also be more in line with the CDCs reference value of 5 ug/dL. Moreover, once a child has tested high the home should be automatically inspected to determine if it is the source of poisoning. Testing "repeatedly and persistently" at elevated levels, does a disservice to our children and uses them as modern day canaries in the mines and reduces them to lead detectors.	None. This amendment pertains to identifying children in need of testing and establishing a schedule of testing for those in need. It does not address blood lead levels at which remedial actions should be taken or specific actions that are recommended in response to elevated levels. The reportable blood lead level is being addressed in a separate regulatory action, and specific actions taken at various levels are determined by public health procedures and clinical standards of practice rather than by regulation.

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

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-120		Regulations for testing children for elevated blood lead levels	Repealed and replaced with the new regulation, cited below.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-90-215	Testing children at 12 and 24 months of age for blood lead levels if they meet any of a list of criteria; confirming tests indicating elevated levels if the test was not a standard confirmatory test performed by a certified laboratory; providing test results to parents or guardians.	Similar requirement exists in 12VAC5-120, which is being repealed within this same regulatory action.	Physicians will need to assess children and determine if they meet criteria for testing for blood lead levels and provide the results and educational materials to parents/guardians for any laboratory results that indicate the child was exposed to lead. This is already a standard of practice for clinicians and a recommendation of the Centers for Disease Control and Prevention. Similar requirements are in effect in an existing agency regulation, except that the blood lead level that indicates that exposure to lead has occurred has been lowered so action will be necessary for children testing at a level lower than previously, which is again an existing standard of practice.